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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

In re DYNAVAX TECHNOLOGIES CORPORATION SECURITIES LITIGATION	Case No. 3:13-CV-02796-CRB **SECOND AMENDED CLASS ACTION COMPLAINT**
This Document Relates To: ALL ACTIONS	

The allegations in this Amended Consolidated Class Action Complaint are based on the personal knowledge of Khaled Khalafallah ("Khalafallah" or "Lead Plaintiff") and Ron Franklin ("Franklin," collectively with Khalafallah "Plaintiffs") as to Plaintiffs' own acts, and are based upon information and belief as to all other matters alleged herein. Plaintiffs' information and belief is based upon the investigation by Plaintiffs' counsel into the facts and circumstances alleged herein, including, without limitation, (i) review and analysis of public filings Dynavax Technologies Corporation ("Dynavax" or the "Company") made with the United States Securities and Exchange Commission ("SEC") referenced herein; (ii) review and analysis of filings Dynavax made with, and documents maintained by, the U.S. Food and Drug Administration ("FDA") referenced herein; (iii) review and analysis of press releases, analyst reports, public statements, news articles and other publications disseminated by or concerning Dynavax and the other defendants named herein (together with Dynavax, the "Defendants") referenced herein; (iv) review and analysis of Company conference calls, press conferences, and related statements and materials referenced herein; and (v) interviews with confidential witnesses referenced herein. Many additional facts supporting the allegations herein are known only to Defendants and/or are within their exclusive custody or control and/or in the custody and control of the FDA which have been withheld based upon claims of confidentiality ***and as a result of ongoing law enforcement investigations***. Plaintiffs believe that additional evidentiary support for the allegations herein will emerge after a reasonable opportunity to conduct discovery.

NATURE OF ACTION

1. This is a federal class action on behalf of investors who purchased or otherwise acquired Dynavax securities between April 26, 2012 and June 10, 2013, inclusive (the "Class Period"), seeking to pursue remedies under Section 10(b), 20A and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder. These claims are asserted against Dynavax and certain of its officers and directors who made materially false and/or misleading statements and/or omissions during the Class Period in, *inter alia*, press

releases, analyst conference calls, and filings with the SEC, and against certain shareholders who sold shares while in possession of material nonpublic information.

2. Dynavax is a clinical-stage biopharmaceutical company that discovers and develops novel products to prevent and treat infectious and inflammatory diseases. The Company's lead product candidate, HEPLISAV, is a Phase III investigational adult hepatitis B vaccine designed to provide higher and earlier protection with fewer doses than currently licensed vaccines. HEPLISAV combines the same hepatitis B surface antigen (the substance provoking the immune response) contained in three other vaccines already licensed and approved by the FDA with Dynavax's totally novel and proprietary ISS 1018 adjuvant (the substance enhancing the immune response to the antigen), a Toll-like receptor 9 ("TLR9") agonist. Defendants knew that no other vaccine containing a TLR9 adjuvant had ever been approved by the FDA.

3. Both prior to and throughout the Class Period, Dynavax faced serious financial pressures to raise the financing needed to complete the clinical trials required to obtain FDA approval for HEPLISAV and bring the product to market. These pressures only increased when Merck & Co., Inc. ("Merck"), the Company's development partner for HEPLISAV, terminated the partnership after the FDA put a clinical hold on all HEPLISAV trials when one subject in pivotal Phase III trial DV2-HBV-10 developed Wegeners granulomatosis, a rare multisystem ***autoimmune*** disease that the independent investigator determined was "***serious, severe, and 'possibly related' to study treatment***."[1]

4. Dynavax had a long history of telling investors that its most recent private or public financing had raised sufficient funds to complete the testing of HEPLISAV and bring the vaccine to market. Indeed, in November 2009, after amending a complicated financing transaction with Symphony Capital LLC and related entities, a fund controlled by Defendant Mark Kessel ("Kessel"), to raise yet another $20 million, CEO Dina told investors "[t]his

[1] All emphases added unless stated otherwise.

transaction is an important milestone for Dynavax, providing approximately $20 million in cash to fund HEPLISAV, which represents the majority of the funding needed for the Phase 3 registration trials for our investigational adult hepatitis B vaccine." Nevertheless, by the end of 2009, after Merck terminated the development partnership, Dynavax was faced with a quarterly burn rate of over $16 million, no commercial products, a $15 million promissory note to Kessel's Symphony entities coming due, no products for which a Biologics License Application ("BLA") had been submitted to the FDA for licensing, and insufficient cash on hand to complete the clinical testing needed to properly support a BLA capable of obtaining FDA licensing. Dynavax hastily prepared HEPLISAV's regulatory application despite knowing or recklessly disregarding the fact that the Company and its BLA lacked sufficient data to demonstrate that the Company could consistently manufacture HEPLISAV vaccines consistent with FDA manufacturing requirements.

5. On April 26, 2012, Dynavax announced it had submitted the BLA to the FDA for its lead product HEPLISAV, seeking approval for the vaccine against infection caused by all known subtypes of hepatitis B virus in adults ages 18-70. Defendants knew or recklessly disregarded, but failed to inform investors, that the BLA did not contain sufficient manufacturing data needed to obtain FDA approval, the Company's manufacturing processes had yet to be validated to ensure that Dynavax's process was capable of consistently delivering quality product, and the BLA excluded critical data pertaining to manufacturing and controls.

6. Nevertheless, throughout the Class Period, Defendants violated the federal securities laws by disseminating false and misleading statements and/or omissions to the investing public concerning the viability of the Company's BLA for HEPLISAV submitted to the FDA. As a result of these false and/or misleading statements and/or omissions, Dynavax's stock traded at artificially inflated prices during the Class Period, reaching a high of $5.26 per share on May 2, 2012.

7. Just 13 days after filing the BLA, Dynavax announced a public offering, which closed on or about May 14, 2012, of 17,500,000 shares at a price of $4.25 per share (the "May

2012 Offering") to raise approximately $74.4 million in gross proceeds. Defendants claimed the proceeds from the offering would be used to fund the commercial launch of HEPLISAV, including the manufacture of commercial supply, marketing, sales, and medical affairs infrastructure and personnel, as well as the hiring of a field sales force, necessary to commercialize HEPLISAV in the United States.

8. Between August 16 and 23, 2012, the FDA conducted an inspection of the Company's HEPLISAV manufacturing facility in Dusseldorf. As a result of the inspection, the FDA issued a Form 483 recording "Inspection Observations" noting twenty-seven separate manufacturing related significant objectionable conditions, some of which dated back to 2011 ("Form 483"). These were not minor violations as such Inspection Observations are "***intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations . . . observed during the inspection.***" FDA Investigations Operations Manual § 5.2.3. This Form 483 was not disclosed to investors, and the Lead Plaintiff was only able to obtain a redacted copy of the Form 483 through multiple Freedom of Information Act ("FOIA") requests. Moreover, in response to Lead Plaintiff's FOIA requests an additional "Two Establishment Inspection Reports" ("Law Enforcement EIR's") were ***withheld by the FDA on the grounds that that they were "Records or information compiled for law enforcement purposes" and their disclosure "could reasonably be expected to interfere with enforcement proceedings."***

9. In October 2012, just weeks after the failed Dusseldorf inspection and a month before the FDA's Vaccines and Related Biological Products Advisory Committee ("VRBPAC") was scheduled to meet, the Company amended and restated defendant Chief Medical Officer ("CMO") J. Tyler Martin's ("Martin") Management Continuity and Severance Agreement to provide for his ultimate departure from Dynavax, rather than his transition to CEO, and announced the search for a new outside CEO to replace Dina. Additionally, on October 16, 2012, Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC, two entities under Kessel's control, for the first time ever sold 6,000,000 shares of Company stock—***or two***

thirds of Kessel's beneficial holdings—at $4.72604 per share for total proceeds of $28,356,000, without disclosure of the Form 483, the manufacturing problems identified therein, the defects in the Company's BLA, and the Company's failure to have validated all manufacturing processes by the time the BLA was submitted.

10. Then, on November 15, 2012, Dynavax attended a meeting before the VRBPAC to discuss the safety and efficacy of HEPLISAV. While the VRBPAC voted 13 to 1 that the data presented in HEPLISAV's application supported the efficacy of HEPLISAV, the committee determined that there was insufficient data to adequately support the safety of HEPLISAV, citing among the committee's concerns the relatively small number of subjects in the safety database, lack of demographic diversity in the study population, and the failure to test or co-administer HEPLISAV with other common vaccines, such as flu vaccines.

11. On February 25, 2013, the Company announced that it received a Complete Response Letter ("CRL") from the FDA regarding its BLA for HEPLISAV, which indicated that the FDA could not approve HEPLISAV without additional safety data, additional data from Dynavax's process validation program, and clarifying information on the manufacturing controls and facilities related to the assurance of the quality of the commercial product. Nevertheless, the Company announced the FDA had indicated a willingness to consider approving a more focused label for HEPLISAV based on the safety data the Company already presented to the FDA. Defendant Dina stated on the same day that the Company "intend[s] to seek a path forward towards approval in a more-focused population, which may be achievable without an additional clinical study."

12. On this news, Dynavax stock declined $0.96 per share, or 32.32%, to close on February 25, 2013 at $2.01 per share, on unusually heavy volume.

13. Then, on June 10, 2013, Dynavax announced that it had recently concluded a follow-up meeting with the FDA regarding its BLA for HEPLISAV. According to the Company, the FDA indicated that the Company's safety database needs additional patients to support approval for any indication, which would ultimately require Dynavax to conduct

additional safety trials before the FDA would even consider approving HEPLISAV, despite the Company's prior statements to the contrary. While the Company had previously indicated that the FDA could consider approving HEPLISAV for discrete patient populations, the Company announced that this approach did not address the fundamental issue of a shortfall in the safety database. Additionally, the Company acknowledged that it still needed to resolve the outstanding manufacturing and control issues with the FDA.

14. On this news, Dynavax's stock plummeted $1.07 or 43.32%, to close on June 10, 2013 at $1.40 per share, on unusually heavy volume.

15. The Company has since admitted that the testing required to present adequate safety data will incur between $50 and $55 million in additional external costs, necessitating yet another public offering of 79,570,000 shares of its common stock at just $1.075 per share, together with an offering of 43,430 shares of Series B Convertible Preferred Stock ("Series B")—not for commercialization, but to fund "additional Phase 3 study of HEPLISAV™ and seeking regulatory approval to commercialize the vaccine."

16. The true facts, which were known and/or recklessly disregarded by Defendants but concealed from the investing public during the Class Period, were as follows:

(a) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements;

(b) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements;

(c) Dynavax's Dusseldorf manufacturing facility failed its pre-approval inspection;

(d) Following the pre-approval inspection of the Company's Dusseldorf manufacturing facility, a Form 483 was issued identifying twenty-seven different significant objectionable conditions; and

(e) Defendants stated the FDA remained open to approval of the vaccine for a more restricted use, but failed to disclose fully the outstanding manufacturing issues and Form 483 that likely precluded such an approval for a more restricted use.

17. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

18. This action arises under Sections 10(b), 20A, and 20(a) of the Exchange Act of 1934, as amended, 15 U.S.C. §§ 78j(b), 78t-1, and 78t, and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

19. This Court has jurisdiction over the action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

20. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. § 78aa. Dynavax maintains its principal place of business in this District. Certain of the acts and conduct complained of herein, including dissemination of materially false and misleading information to the investing public, occurred in this District.

21. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

Lead Plaintiff

22. Lead Plaintiff Khaled Khalafallah, as set forth in his shareholder certification (ECF No. 12-6), purchased Dynavax stock at artificially inflated prices during the Class Period and has been damaged thereby.

23. Plaintiff Ron Franklin, as set forth in his shareholder certification (ECF No. 65-1), purchased Dynavax stock on various dates at artificially inflated prices during the Class Period, including 255 shares on October 18, 2012 at $4.70 per share, and has been damaged thereby.

Dynavax Technologies Corporation

24. Defendant Dynavax is a Delaware corporation with its principal executive offices located at 2929 Seventh Street, Suite 100, Berkeley, CA 94710-2753. Dynavax is a clinical-stage biopharmaceutical company, which discovers and develops novel products to prevent and treat infectious and inflammatory diseases. The Company's lead product candidate, and the subject of this action, is HEPLISAV, a Phase III investigational adult hepatitis B vaccine designed to provide higher and earlier protection with fewer doses than currently licensed vaccines.

The Individual Defendants

25. Defendant Dino Dina was, until May 1, 2013, the Company's Chief Executive Officer. Dina remains a director of the Company and also continues to serve the Company as a consultant. Dina received compensation of $2.89 million in 2012 for his role as CEO. Because of his positions with the Company, Dina had access to the adverse, undisclosed information concerning the inadequate safety database for HEPLISAV's Phase III trials, the validation program and manufacturing controls at the facilities related to the assurance of the quality of the commercial product for HEPLISAV, the Form 483 and the manufacturing problems identified therein, the prospects for FDA approval, and all material facts concerning the submission of HEPLISAV's BLA to the FDA. Dina directly participated in and controlled the management of the Company, including, without limitation, day-to-day decisions concerning the development of

HEPLISAV, submission of the BLA to the FDA, publication of statements made to the investing public, the SEC, and the FDA concerning the safety, efficacy and manufacture of HEPLISAV, and publication of statements by and on behalf of Dynavax concerning HEPLISAV in the Company's press releases, SEC filings, and other public statements.

26. Defendant J. Tyler Martin was, until his departure on May 31, 2013, the Company's President and CMO. Martin received compensation of $2.51 million in 2012 for his role as President and CMO. Because of his positions with the Company, Martin had access to the adverse, undisclosed information concerning Dynavax's validation program and manufacturing controls at the facilities related to the assurance of the quality of the commercial product for HEPLISAV, the Form 483 and the manufacturing problems identified therein, the prospects for FDA approval, and all material facts concerning the submission of HEPLISAV's BLA to the FDA. Martin directly participated in and controlled the management of the Company, including, without limitation, day-to-day decisions concerning the development of HEPLISAV, submission of the BLA to the FDA, publication of statements made to the investing public, the SEC, and the FDA concerning the safety, efficacy and manufacture of HEPLISAV, and publication of statements by and on behalf of Dynavax concerning HEPLISAV in the Company's press releases, SEC filings, and other public statements.

27. Defendant Mark Kessel became a member of the Board in December 2009. Kessel has written on financing for the biotech industry for Nature Reviews Drug Discovery, Nature Biotechnology and other publications. Kessel also serves as Of Counsel to Shearman & Sterling LLP, an international law firm, and is widely recognized as a leader in structuring product development investments for the biopharmaceutical industry.

28. The defendants named above in ¶¶ 25-27 are referred to herein as the "Individual Defendants."

29. The Individual Defendants, because of their positions with the Company, had the authority to control, correct and/or update the contents of Dynavax's public disclosures to the market. Each of the Individual Defendants had the duty to exercise due care and diligence and

the duty of full and candid disclosure of all material facts relating to the Company's financial results and operations. The Individual Defendants further had the duty to correct and/or update any previously issued statements that were untrue or became materially misleading or untrue, so that the market price of the Company's publicly traded common stock would be based upon truthful, complete, and accurate information. To discharge their duties, the Individual Defendants were required to exercise reasonable and prudent supervision over the dissemination of information concerning the Company's financial results and operations. By virtue of such duties, these officers and/or directors were required, *inter alia*, to:

a) conduct and supervise the business of Dynavax in accordance with federal laws;

b) supervise the preparation of Dynavax's SEC filings and approve any reports concerning Dynavax's financial reporting and results; and

c) ensure that Dynavax established and followed adequate internal controls.

30. As officers, directors, and/or controlling persons of a publicly-held company which is registered with the SEC under the federal securities laws and the securities of which were traded on the NASDAQ and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to (1) promptly disseminate accurate and truthful information with respect to the Company's financial statements and operations; (2) correct any previously issued statements that were materially misleading or untrue so that the market could accurately price the Company's publicly traded securities based upon truthful, accurate, and complete information; and (3) update any previously-issued statements that became materially misleading or untrue so that the market could accurately price the Company's publicly traded securities based upon truthful, accurate, and complete information.

31. The Individual Defendants are each primarily liable for the misrepresentations and misleading statements alleged herein and are also liable as controlling persons of Dynavax. The scheme deceived the investing public regarding Dynavax's submission of the HEPLISAV BLA to the FDA and the manufacturing problems identified in the Form 483, which caused

Plaintiffs and other members of the Class to purchase Dynavax securities at artificially inflated prices during the Class Period and suffer damages as a result.

Symphony Entities

32. Nonparty Symphony Capital LLC, is a Delaware limited liability company and promotes itself as a private equity firm dedicated to collaborating with leading innovative biopharmaceutical companies, helping them capture more of the value in their most important clinical development programs. Symphony Capital LLC was co-founded by Defendant Kessel in 2002. Symphony Capital LLC operates through related entities, including the following Defendants: (1) Symphony Capital Partners, L.P. ("SCP LP"), a Delaware limited partnership; (2) Symphony Capital GP, L.P. ("SCP GP"), a Delaware limited partnership and the general partner of SCP LP; (3) Symphony GP, LLC ("SGP LLC"), the general partner of SCP GP; and Symphony Strategic Partners, LLC ("SSP LLC"), a Delaware limited liability company.

33. Defendant Kessel is a Managing Member of SGP LLC, which is the general partner of SCP GP, which is the general partner of SCP LP; and Kessel is also a Managing Member of SSP LLC, and as such is authorized to vote and dispose of the Dynavax securities held by SCP LP and SSP LLC.

34. As a co-founder of Symphony Capital LLC, Kessel developed a business model where Symphony Capital LLC or its affiliated entities would create a company which would in-license two or more drugs from a biotech company. The Symphony entities would then commit a specific amount of capital designed to take the drugs through proof of concept, and then give the company the right to buy back the drugs at a predetermined price. Pursuant to this model, in 2006, Kessel created Symphony Dynamo, Inc. ("SDI") in which the Symphony entities and affiliated investors funded $50M for the development of three Dynavax drug candidates: 1018 ISS for cancer, a second-generation ISS for hepatitis C, and a hepatitis B therapeutic. In exchange, Dynavax (1) assigned its rights in the three drugs; (2) assigned its right to receive licensing royalties from the three drugs; and (3) granted SDI's holding company a warrant to purchase 2,000,000 shares of Dynavax common stock at $7.32. Under the financing

arrangement, Dynavax (1) retained the responsibility for development of the three drugs; and (2) received an option to repurchase the rights to the drugs at specified prices. In 2007, Dynavax repurchased its rights to ISS 1018 in exchange for a $15 million promissory note.

35. On November 9, 2009, Dynavax and the Symphony entities amended the financing transaction whereby Dynavax repurchased SDI. Under this amendment, Dynavax obtained approximately $20 million then remaining in Dynamo, along with any intellectual property rights still held by SDI or its holding company. In exchange, Dynavax issued SCP LP 7,910,764 shares of Dynavax common stock and issued SSP LLC 430,036 shares of Dynavax common stock, for a total of 8,340,800 shares of Dynavax common stock;[2] cancelled 1,217,040 warrants to purchase Dynavax common stock held by SCP LP and 66,160 warrants held by SSP LLC, for a total of 1,283,200 previously issued warrants with an exercise price of $7.32 per share and issued a corresponding number of new warrants to each Symphony entity with an exercise price of $ 1.94 per share;[3] and granted the Symphony Defendants the right to receive 50% of the first $50 million Dynavax received from any commercialization of its cancer or hepatitis C therapies. Notably, the amendment also granted the Symphony related entities the right to designate one member of the Board, i.e., Kessel and one independent director acceptable to both Symphony and Dynavax, as long as Symphony's ownership of total Dynavax common stock outstanding exceeded 10%.

Confidential Witnesses

36. Confidential witness #1 was employed by Dynavax from June 2006 until June 2010 ("CW1"). From June 2006 until September 2007, CW1 served as a Clinical Research Associate and then as a Senior Clinical Research Associate for the remainder of CW1's tenure. In this role, CW1 was responsible for managing clinical research studies for HEPLISAV. CW1

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[2] The shares were actually issued to special purpose holding company, which in turn issued shares to SCP LP, SSP LLC, and affiliated investors. SCP LP, SSP LLC, and the affiliated investors, however, were deemed and reported as the holder of securities in Dynavax. A total of 13 million shares were issued, but 4,659,200 were issued to affiliated investors.

[3] A total of 2 million warrants were re-priced, including those issued to affiliated investors.

had direct interaction with defendant Martin. According to CW1, Martin was actively involved in responding to and communicating with the FDA. Moreover, Martin's "finger was on the pulse" of the Phase III trials. CW1 further said Martin knew the study like he was running it and was very involved. CW1 described Martin as invested in and heavily pushing for HEPLISAV.

37. Confidential witness #2 was employed by Dynavax as the Executive Assistant to defendant Martin from 2010 to 2011 ("CW2"). CW2 described Martin as aggressive in pursuing FDA approval of the vaccine, and CW2 heard from other employees that Martin had an aggressive timeline for compiling and submitting the BLA. Other employees complained to CW2 that Martin was "crazy" and that his timelines were unrealistic. According to CW2, Martin received "pre-packets" from various Dynavax direct reports, which were early compilations of data for the BLA submission. According to CW2, Martin reviewed these pre-packets meticulously. According to CW2, Vice President of Regulatory Affairs William Turner ("Turner") and Vice President of Clinical Development William Heyward reported directly to Martin and met with him frequently.

38. Confidential witness #3 was employed by Dynavax as a Research Associate for pre-clinical testing from 2007 until 2010 ("CW3"). CW3 subsequently returned to Dynavax in a similar role from January through March 2013. CW3 described HEPLISAV as "Dino's baby."

39. Confidential witness #4 was employed by Dynavax as Vice President of Clinical Development/Clinical Trials from March 2006 to December 2008 ("CW4"). CW4 initially reported directly to defendant Dina, though soon after starting at Dynavax, CW4 began reporting to Martin Sanders, who reported to Dina. CW4 was responsible for designing the first Phase III clinical trial for HEPLISAV, which was conducted in Canada and Europe in accordance with guidelines from Health Canada, a Canadian regulatory agency, and the Paul Ehrlich Institute, a German regulatory agency. According to CW4, defendant Martin succeeded CW4 when CW4 left the Company, and took over responsibility for designing HEPLISAV's clinical trials. CW4 stated that he/she "could not conceive of a study [being conducted] that was not approved by Tyler [Martin]."

40. Confidential witness #5 was employed by Dynavax as a Director dealing with manufacturing from July 2011 until December 2011 ("CW5"). In this position, CW5 reported to Vice President of Technical Operations Stephen Tuck ("Tuck"). CW5 believed Tuck reported to defendants Martin or Dina. During this tenure at Dynavax, CW5 was responsible for the oligonucleotide technology, which, as CW5 explained, meant the adjuvant component of the HEPLISAV vaccine. As a Ph.D. with a background as a scientist, CW5 oversaw the manufacturing and production (referred to as the Chemistry, Manufacturing and Controls, or "CMC") of the adjuvant, which CW5 described as the core technology of the vaccine. In this role, CW5 was also responsible for assisting with writing, adding, and interpreting data for the section of the BLA pertaining mainly to the manufacturing and production of the adjuvant. According to CW5, this section alone contained approximately 700 to 800 pages of text.

41. In the first week of employment at Dynavax, CW5 learned that the four people who held his position before him had been fired. In fact, CW5's first task was to fire the person performing these duties prior to CW5's hire. Given the history of the position, CW5 believed that if HEPLISAV was not approved due to a deficiency in this section, CW5 would be fired. As such, when CW5 noticed information he believed was required by the FDA for a successful BLA he brought the issue to Tuck's attention and made a "big deal." However, on one specific item addressed below, CW5 indicated that Tuck refused to address a key omission.

42. Confidential witness #6 was employed by Dynavax as Associate Director, Regulatory Affairs beginning in November 2006 until January 2014 ("CW6"). CW6 initially reported directly to VP, Regulatory Affairs Turner. Upon the hiring of Director, Regulatory Affairs Elaine Alambra ("Alambra"), CW6 began reporting to Alambra, who in turn reported to Turner. According to CW6, Turner reported to Defendant Dina (except for one month when Turner reported to EVP Marty Sanders) until the hiring of Defendant Martin, at which time Turner reported to Martin. Then, in 2013, Turner reported to newly hired CEO Eddie Gray.

43. In her position, CW6 worked on regulatory affairs for the HEPLISAV vaccine. CW6 was responsible for regulatory issues involving HEPLISAV and worked on the BLA.

44. CW6 was present during the FDA inspection of the Dusseldorf facility in August 2012, though CW6 had to return to the United States before the inspection was over because of information requests ("IRs") received from the FDA pertaining to the BLA application. CW6 noted that there were other individuals from Dynavax present during the inspection, including VP Turner and VP Technical Operations Tuck. CW6 has stated the Form 483 was given to Rhein Biotech, GmbH ("Rhein Biotech") (a Dynavax subsidiary) CEO Zbigniew Janowicz on-site at the close of the inspection. Janowicz then would have reported the results of the Form 483 directly to Defendants Dina and Martin. CW6 has confirmed that each of the issues raised in the Form 483 were all CMC and facility-related issues pertaining to quality.

SUBSTANTIVE ALLEGATIONS

Background Of The Company, Hepatitis B And HEPLISAV

45. Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. The Company's leading product candidate, HEPLISAV, is an investigational adult hepatitis B vaccine for which U.S. and European licensure applications have been accepted for review by the FDA and the European Medicines Agency, respectively. HEPLISAV combines hepatitis B surface antigen with a novel, proprietary TLR-9 agonist to enhance the immune response. HEPLISAV was designed to provide higher and earlier protection with fewer doses than currently licensed vaccines.

46. Vaccines for the prevention of hepatitis B have been routinely used since the early 1980s. Hepatitis B vaccines consist of two effective components: the antigen and the adjuvant. An antigen resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. An adjuvant is a pharmacological and/or immunological agent that enhances the immune response to an antigen.

47. In the case of currently FDA licensed and approved hepatitis B vaccines, namely GlaxoSmithKline's Engerix B and its Twinrix combination vaccine, as well as Merck's Recombivax HB vaccines, the antigen consists of HBsAg, which is the surface antigen of the

hepatitis B virus developed from yeast cultures. The adjuvant used in each of these vaccines is alum (aluminum hydroxide). Alum is one of the most common adjuvants used in a broad spectrum of vaccines with a long history of safety beginning in the 1920's. Each of these approved vaccines is given in three doses over a course of months.

48. The antigen contained in Dynavax's experimental HEPLISAV vaccine, like the currently licensed hepatitis B vaccines, is yeast-derived recombinant HBsAg. HEPLISAV, however, contains a totally novel adjuvant named ISS 1018. ISS 1018 is an immunostimulatory sequence ("ISS") consisting of short deoxyribonucleic acid ("DNA") sequences that targets Toll-like receptor 9 ("TLR9"). According to Dynavax's public filings with the SEC, Dynavax claims "ISS work by changing or reprogramming the immune responses that cause disease rather than just by treating the symptoms of the disease. Since TLR9 is found exclusively in a specialized subset of dendritic cells, ISS do not cause a generalized activation of the immune system and redirect the response of only those T-cells involved in a given disease. When linked to or combined with antigens, ISS help generate memory T Helper ("Th") 1 cells that can reprogram the immune system to induce long-lasting therapeutic effects." ISS 1018, the adjuvant containing the TLR9 agonist, is manufactured by a third party in Massachusetts. The hepatitis B surface antigen is manufactured at the Company's facility in Dusseldorf, Germany, owned by Dynavax's Rhein Biotech subsidiary.

49. Toll-like receptors ("TLRs") were first identified in humans and reported in the 1990's. Subsequent research has been conducted to determine their role and utility in immunology. One recently approved vaccine, Cervarix, contains the proprietary lipid-based AS04 adjuvant system targeting TLR4. To date, however, no vaccine has been approved which contains ISS or which targets TLR9. Thus, HEPLISAV contains a totally novel and previously untested adjuvant with a unique mechanism of action.

The Biologics License Application For HEPLISAV

50. Originally, Merck and Dynavax engaged in a partnership to jointly develop HEPLISAV. Pursuant to this partnership, Merck and Dynavax jointly commenced a Phase III

study, DV2-HBV-10, of the safety and effectiveness of HEPLISAV. Study DV2-HBV-10 enrolled 2,428 low hepatitis B risk male and female subjects 11-55 years of age who had never received any prior hepatitis B vaccine. Of these enrollees, 1,809 were injected with two doses of HEPLISAV.

51. During the course of study DV2-HBV-10, a subject was diagnosed with Wegeners granulomatosis, a rare multisystem autoimmune disease. The investigator assessed the event as "serious, severe, and 'possibly related' to study treatment." As a result of this severe side effect, the FDA placed a clinical hold on all HEPLISAV clinical trials. Then in October 2008, since there were already three licensed safe and effective hepatitis B vaccines available, the FDA notified Dynavax that "the balance of risk versus potential benefit no longer favors continued clinical evaluation of HEPLISAV in healthy adults and children. The FDA has also advised the companies that there may be potential for an acceptable risk versus benefit profile for HEPLISAV in patients with renal failure, and requested additional information from the companies before considering further pursuit of clinical studies in those patients." Then in December 2008, Merck terminated its partnership with Dynavax and retired its rights to HEPLISAV.

52. Thereafter, Dynavax worked with the FDA, and in September 2009 the FDA removed the hold on HEPLISAV trials. Subsequently Dynavax initiated DV2-HBV-16, a Phase III safety, efficacy, and lot-to-lot consistency trial. Study DV2-HBV-16 enrolled 2,452 low hepatitis B risk male and female subjects 40-70 years of age who had never received any prior hepatitis B vaccine. Of these enrollees, 2,269 subjects completed the study and 1,968 were injected with at least one dose of HEPLISAV.

53. In 2009, after the FDA had approved the resumption of HEPLISAV trials, the financing arrangement between the Symphony-related entities and affiliated investors on the one hand and Dynavax on the other hand was amended, transferring the equity in SDI and the products back to Dynavax, and, in exchange, Dynavax (1) issued 13 million shares of Dynavax common stock to Symphony related investors, of which SCP LP 7,910,764 shares were issued to

SCP LP and 430,036 shares to SSP LLC; (2) effectively re-priced previously issued warrants to purchase 2,000,000 shares, of which 1,217,040 warrants were held by SCP LP and 66,160 by SSP LLC, from $7.32 to just $1.94; (3) deferred the existing $15 million obligation due to Symphony by 20 months (until December 31, 2012) and converted the obligation previously payable solely in cash, to payable in stock and/or cash at Dynavax's election; and (4) granted the Symphony-related entities 50% of the first $50 million from any potential upfront and development milestones received by Dynavax for hepatitis C and cancer therapies drug candidates.

54. On January 8, 2010, Dynavax filed a Registration Statement on Form S-3 ("Registration Statement") registering a total of 15 million shares of common stock, representing the 13 million shares of common stock and the 2 million shares underlying the warrants issued in the amended financing transaction.

55. With respect to the Company's manufacturing facilities, the Registration Statement contained the following risk factors:

> If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review.
>
> Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or long-term use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.
>
> In addition, we or our contract manufacturers will be required to adhere to federal regulations setting forth current good manufacturing practice. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control activities. ***Furthermore, we or our contract manufacturers must pass a pre-approval inspection of manufacturing facilities by the FDA and foreign regulatory agencies before obtaining marketing approval and will be subject to periodic inspection by the FDA and corresponding foreign regulatory agencies under reciprocal agreements with the FDA***. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

* * *

We rely on third parties and our facility in Düsseldorf, Germany to supply materials necessary to manufacture our clinical product candidates for our clinical trials. Loss of these suppliers or key employees in Düsseldorf, or failure to timely replace them may delay our clinical trials and research and development efforts and may result in additional costs, delays or significantly higher costs in manufacturing our product candidates.

We rely on a number of third parties and our facility in Düsseldorf for the multiple steps involved in the manufacturing process of our product candidates, including, for example, ISS, a key component material that is necessary for our product candidates, the production of certain antigens, the combination of the antigens and ISS, and the fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development efforts.

We and these third parties are required to comply with applicable FDA current good manufacturing practice regulations and other international regulatory requirements. If one of these parties fails to maintain compliance with these regulations, the production of our product candidates could be interrupted, resulting in delays and additional costs. Additionally, these third parties and our manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates.

We have relied on a single supplier to produce our ISS for clinical trials. To date, we have manufactured only small quantities of ISS ourselves for research purposes. If we were unable to maintain or replace our existing source for ISS, we would have to establish internal ISS manufacturing capability which would result in increased capital and operating costs and delays in developing and commercializing our product candidates. We or other third parties may not be able to produce ISS at a cost, quantity and quality that are available from our current third-party supplier.

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. If HEPLISAV cannot be successfully developed or is not commercially viable, we will have to use the Düsseldorf facility for alternative manufacturing or research activities that may not fully utilize the facility's capacity, resulting in continued operating costs that may not be offset by corresponding revenues, or we may consider other alternatives for the Düsseldorf facility, including its sale or closure which would result in certain costs of disposal or discontinuation of operations.

56. On April 26, 2012, Dynavax announced it had submitted its BLA to the FDA for its lead product HEPLISAV, seeking approval for the vaccine against infection caused by all known subtypes of the hepatitis B virus in adults ages 18-70. The contents of the BLA have never been made public or revealed to investors.

57. The FDA describes the BLA process as follows:

> FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines in the United States. Current authority for the regulation of vaccines resides primarily in Section 351 of the Public Health Service Act and specific sections of the Federal Food, Drug and Cosmetic Act.
>
> Vaccine clinical development follows the same general pathway as for drugs and other biologics. A sponsor who wishes to begin clinical trials with a vaccine must submit an Investigational New Drug application (IND) to FDA. The IND describes the vaccine, its method of manufacture, and quality control tests for release. Also included are information about the vaccine's safety and ability to elicit a protective immune response (immunogenicity) in animal testing, as well as the proposed clinical protocol for studies in humans.
>
> Pre-marketing (pre-licensure) vaccine clinical trials are typically done in three phases, as is the case for any drug or biologic. Initial human studies, referred to as Phase 1, are safety and immunogenicity studies performed in a small number of closely monitored subjects. Phase 2 studies are dose-ranging studies and may enroll hundreds of subjects. Finally, Phase 3 trials typically enroll thousands of individuals and provide the critical documentation of effectiveness and important additional safety data required for licensing. At any stage of the clinical or animal studies, if data raise significant concerns about either safety or effectiveness, FDA may request additional information or studies, or may halt ongoing clinical studies.
>
> If successful, the completion of all three phases of clinical development can be followed by the submission of a Biologics License Application (BLA). To be considered, the license application must provide the multidisciplinary FDA reviewer team (medical officers, microbiologists, chemists, biostatisticians, etc.) with the efficacy and safety information necessary to make a risk/benefit assessment and to recommend or oppose the approval of a vaccine. ***Also during this stage, the proposed manufacturing facility undergoes a pre-approval inspection during which production of the vaccine as it is in progress is examined in detail.***
>
> Following FDA's review of a license application for a new indication, the sponsor and the FDA may present their findings to FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). This non-FDA expert committee (scientists, physicians, biostatisticians, and a consumer representative) provides advice to the Agency regarding the safety and efficacy of the vaccine for the proposed indication.

Manufacturing And Controls Of The Antigen And Adjuvant

58. As part of the BLA approval process for HEPLISAV, Dynavax was required to demonstrate that its manufacturing processes and facilities, or those of the Company's third-party contract manufacturers and suppliers, met Good Manufacturing Practice ("GMP") requirements before the Company could utilize those facilities in the commercial manufacture of HEPLISAV.[4] Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the "Act") (21 U.S.C. § 351(a)(2)(B)). These GMP requirements mandate that product candidates be manufactured and records maintained in a prescribed manner with respect to manufacturing, testing, and quality control/quality assurance activities. As explained by the FDA, GMP "regulations require that manufacturing processes be designed and controlled to assure that in-process materials and ***the finished product meet predetermined quality requirements and do so consistently and reliably.***" FDA Guidance on Process Validation at 6. Deficiencies in any part of the BLA pertaining to the manufacturing processes or facilities or those of the Company's third-party contract manufacturers and suppliers could result in delay, limitation, or denial of the HEPLISAV BLA. 21 CFR §610.20(c)-(d).

59. The approval of the manufacturing process is referred to as Process Validation, which consists of three stages: (1) process design; (2) process qualification; and (3) continued process verification. Process design is the activity of defining the commercial manufacturing process that will be reflected in planned master production and control records. Once the manufacturing process has been properly designed, a multi-step process qualification procedure is employed to obtain approval or qualification of the manufacturing process. The process qualification has two elements: "(1) design of the facility and qualification of the equipment and utilities and (2) process performance qualification (PPQ). During Stage 2, CGMP-compliant procedures must be followed. Successful completion of Stage 2 is necessary before commercial

[4] The FDA has defined "commercial manufacturing process" as "[t]he manufacturing process resulting in commercial product (i.e., drug that is marketed, distributed, and sold or intended to be sold)." FDA, Guidance for Industry: Process Validation: General Principles and Practices, January 2011 ("FDA Guidance on Process Validation").

distribution." FDA Guidance on Process Validation at 13. PPQ requires "a higher level of sampling, additional testing, and greater scrutiny of process performance than would be typical of routine commercial production. ***The level of monitoring and testing should be sufficient to confirm uniform product quality throughout the batch.***" *Id.* at 12. The company then must evaluate the data in a validation procedure using "[c]riteria and process performance indicators that allow for a science- and risk-based decision about the ability of the process to consistently produce quality products." *Id.* at 13. Until both steps of the PPQ step are completed, the BLA for the vaccine will not be approved and the vaccine cannot be commercially manufactured or distributed, except in extraordinary circumstances.[5] Once the vaccine has been approved, the vaccine is then subject to a third stage of continued process verification of the quality and consistency of the commercially manufactured and distributed product.

60. CW5 was responsible for the CMC portion of the BLA pertaining to the adjuvant manufactured by a third party in Massachusetts. According to CW5, a critical piece of the BLA he believed was required by the FDA for a successful BLA as it pertained to manufacturing processes and controls was called Critical Process Parameters ("CPP"). In manufacturing, there are approximately 20 different variables that can alter the outcome of the substance being manufactured; these variables include temperature and concentration. CPP means it is necessary to conduct testing and analysis to determine which variable drives the reaction in the substance. Once the variable is identified, then it is necessary to establish manufacturing specifications that tightly control the variable and ensure that the outcome remains consistent. For instance, analysis might identify temperature as the key variable making it necessary to establish procedures to ensure control of the temperature and maintain a consistent end product. This area

[5] The FDA Guidance on Process Validation, at 19, provides examples of extraordinary circumstances in which commercial distribution and PPQ qualification may be appropriate, such as "drugs for which there is limited demand (e.g., orphan drugs, minor use and minor species veterinary drugs) or which have short half-lives (e.g., radiopharmaceuticals, including positron emission tomography drugs). Concurrent release might also be appropriate for drugs that are medically necessary and are being manufactured in coordination with the Agency to alleviate a short supply," none of which would apply to HEPLISAV.

was particularly critical in the CMC of the adjuvant, given the role the adjuvant played in the overall chemistry of the vaccine.

61. Through CW5's analysis of the manufacturing and controls data to be submitted in the BLA, CW5 identified missing CPP data. CW5 believed the CPP data for the vaccine's adjuvant was required by the FDA for a successful BLA. CW5 proposed a strategy to Tuck for compiling and incorporating the data into the BLA, but Tuck rebuffed CW5's attempt to incorporate the CPP data.

62. Thereafter, during a December 2011 concurrence meeting held with each department responsible for information included in the BLA conducted by Turner and attended by Tuck and others, the group reviewed the data and all contents of the section pertaining to the CMC of the adjuvant (CW5's section). CW5 indicated that there was still time to compile and add the CPP data. CW5 explained that he believed the FDA required the CPP data for a successful BLA. However, instead of addressing CW5's very real concerns regarding the missing CPP data, Tuck fired CW5 the next day because CW5 was not a good fit at the company and did not share the company's risk tolerance.

63. Subsequently, CW5 confirmed that the FDA's request for "additional data from the Company's process validation program and its manufacturing controls and facilities, in order to receive assurances regarding the quality of the commercial product," which formed part of the FDA's basis for declining HEPLISAV's approval, likely pertained to the CPP component that the Company intentionally omitted from the BLA.

The FDA Inspection Of The Dusseldorf Manufacturing Facility And The Resulting Form 483 And Law Enforcement Proceedings

64. Between August 16 and 23, 2012, the FDA conducted an inspection of the Company's HEPLISAV manufacturing facility in Dusseldorf. As a result of the inspection, the FDA issued a Form 483 recording "Inspection Observations" noting twenty-seven separate manufacturing related violations, some of which dated back to 2011, a copy of which is attached

as Exhibit A. Defendants never disclosed the Form 483, and it was only obtained by Lead Plaintiff in a heavily redacted form from the FDA pursuant to a FOIA Request.

65. According to the FDA Investigations Operations Manual, a Form 483 is reserved "for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations . . . observed during the inspection." FDA Investigations Operations Manual § 5.2.3. specifically provides:

> The FORM FDA 483 INSPECTIONAL OBSERVATIONS [] is intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts (see IOM 5.2.3.2) which were observed during the inspection. These observations are made when in the investigator's "judgment", conditions or practices observed, indicate that any food, drug, device, or cosmetic have been adulterated or are being prepared, packed, or held under conditions whereby they may become adulterated or rendered injurious to health. The issuance of written inspectional observations is mandated by law and ORA policy.

66. CW6 was present at the Dusseldorf facility during the inspection that generated the Form 483. According to CW6, each of the observations reported in the Form 483 were CMC and facility-related issues pertaining to quality.

67. In response to Lead Plaintiff's FOIA requests, the FDA withheld an additional two Law Enforcement EIR's, claiming that they were "Records or information compiled for law enforcement purposes. . . ." According to the FDA Inspection Operations Manual, § 5.10.1.

> The EIR consists of the following in this order: a printed copy of the FACTS Establishment Inspection Record (EI Record) including, at least, the endorsement with the EIR distribution printed at the bottom of the "endorsement" section of the EI Record; carbon or other copies of FDA forms issued during the inspection such as the FDA 482, FDA 483, and FDA 484; investigator's narrative report; copy of assignment if available; exhibits; and/or any additional material attached and referred to in the narrative report.

The FDA Vaccines And Related Biological Products Advisory Committee Meeting And Complete Response Letter – The BLA's Weaknesses Are Exposed

68. Pursuant to FDA regulations, the FDA is authorized to convene an Advisory Committee panel consisting of industry experts to opine on the advisability of approval for a particular candidate. On November 15, 2012, the FDA VRBPAC convened to discuss

HEPLISAV's BLA and review and evaluate data concerning the safety, effectiveness, and appropriate use of HEPLISAV.

69. On November 15, 2012, in advance of the VRBPAC meeting, the FDA staff published its Briefing Documents detailing its findings regarding the HEPLISAV BLA. According to the Briefing Documents, "the safety database for HEPLISAV may not have sufficient power to detect rare adverse events." Moreover, while the vaccine did not reveal clinically significant safety concerns, "it is acknowledged that the ability to reliably evaluate uncommon specific autoimmune events is limited due to the size of the study." The FDA staff concluded that:

> [G]iven the relatively low incidence of many autoimmune diseases in the general population, the often non-specific initial presentation of these diseases and the limitations imposed by follow up periods, the pre-licensure safety database for this vaccine with a new adjuvant may not have sufficient power to detect rare adverse events. Additionally, the safety database for this new adjuvant is limited to the studies conducted using this product.

70. The VRBPAC was specifically tasked with evaluating only the immunogenicity and safety of HEPLISAV. Ultimately, the VRBPAC panel voted eight to five with one abstention that there was insufficient data to adequately support the safety of HEPLISAV.

71. On February 25, 2013, the Company announced the receipt of the CRL, which, according to Dynavax, specified that the indication in adults 18-70 years of age could not be approved without further evaluation of safety data based on the FDA's continued concerns that novel adjuvants may cause rare autoimmune events. Additionally, the FDA's decision to deny HEPLISAV's approval was based, in part, on Dynavax's failure to provide sufficient process validation program and sufficient data on the manufacturing controls and facilities related to the assurance of the quality of the commercial product, as discussed above. Defendants have never disclosed the contents of the CRL.

The May 2012 Offering

72. On May 9, 2012, just 13 days after filing the BLA for HEPLISAV, Dynavax issued a press release announcing the pricing of an offering of 17,500,000 shares of its common

stock, offered at $4.25 per share for gross proceeds of approximately $74.4 million, before underwriting discounts, commissions, and other offering expenses.

73. For the quarter ending March 31, 2012, HEPLISAV reported cash on hand of $106.9 million immediately before the offering. During the operation of study DV2-HBV-16 and the preparation of the BLA, however, the Company experienced an adjusted average quarterly burn rate of $16.3 million (eliminating non-recurring revenues) combined with declining revenue from collaborations.

74. Dynavax has now announced that external costs of an additional HEPLISAV trial, which will include 5,500 HEPLISAV injected subjects, will total approximately $50-$55 million dollars. In addition, over the past two quarters, the Company has reported dramatically higher general and administrative expenses. Specifically, for the first and second quarters of 2013, Dynavax reported general and administrative expenses of $8.8 million and $7.6 million respectively, compared to $5.9 and $6.0 for the same quarters in 2012.

75. From the second quarter of 2012, when the HEPLISAV BLA was filed, through the second quarter of 2013 when the Company announced the feedback from the FDA with respect to ongoing HEPLISAV trials, Dynavax reported net losses of $77.3 million.

CLASS PERIOD STATEMENTS

76. The Class Period begins on April 26, 2012. On this day, the Company issued a press release announcing the BLA submission to the FDA. The press release stated in relevant part:

> ***Dynavax Technologies Corporation today announced that it has submitted a U.S. Biologics License Application (BLA) to the Food and Drug Administration (FDA) for HEPLISAV, pursuing an indication for immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 through 70 years of age.***
>
> Dynavax President and Chief Medical Officer, Tyler Martin, M.D., said:
>
> ***"This submission is a very important milestone for Dynavax. The final document consists of 305 volumes, and the expansion of the indicated age group following the pre-BLA meeting required complete rewrites of the clinical summaries. The entire HEPLISAV team did outstanding work to complete the revisions and submit the BLA ahead of schedule.*** We have requested priority

> review for HEPLISAV, as we believe it is a significant improvement compared to marketed products. ***We look forward to working with the FDA on the BLA*** and to ultimately bringing the benefits of HEPLISAV to the public."
>
> The Company anticipates submitting a European Marketing Authorization Application (MAA) for HEPLISAV in the third quarter of 2012. Upon approval of the initial HEPLISAV BLA, Dynavax plans to submit a supplemental BLA with an indication and 3-dose primary vaccination regimen for patients with chronic kidney disease.

77. In the wake of submitting the BLA for HEPLISAV to the FDA, Dynavax reached its Class Period high of $5.26 per share on May 2, 2012.

78. Defendants' statements in ¶ 76 were materially false and misleading when made. Defendants knew and/or recklessly disregarded, and failed to disclose, the following:

(a) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements; and

(b) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements.

79. On May 4, 2012, Dynavax filed its Form 10-Q for the quarter ending March 31, 2012 (the "1Q 2012 Form 10-Q"), signed and certified by defendant Dina. In regard to HEPLISAV, the BLA submission, and the Company's business, operations, and prospects, the 1Q 2012 Form 10-Q stated, in relevant part:

> ***In April 2012, we submitted the U.S. Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for HEPLISAV, pursuing an indication for immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 through 70 years of age***. We anticipate submitting a European Marketing Authorization Application for HEPLISAV in the third quarter of 2012. Upon approval of the initial HEPLISAV BLA, we plan to submit a supplemental BLA with an indication and 3-dose primary vaccination regimen for patients with chronic kidney disease.

80. In regard to general regulatory matters concerning the process validation program and manufacturing controls specifically, the 1Q 2012 Form 10-Q contained the following risk factors:

> ***For our lead product, HEPLISAV, our Biologics License Application ("BLA") must be approved by the FDA*** and corresponding applications to foreign regulatory agencies must be submitted and approved by those agencies before we may sell the product. Obtaining approval of a BLA by the FDA and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The BLA review process is extensive, lengthy, expensive and uncertain, and ***the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for HEPLISAV for many reasons, including: . . . deficiencies in our manufacturing processes or facilities*** or those of our third party contract manufacturers and suppliers, if any. . . ***The FDA*** or foreign regulatory agencies ***may determine our*** clinical trials or other ***data regarding*** safety, efficacy or ***consistency of manufacture is insufficient for regulatory approval***.
>
> * * *
>
> ***Prior to granting product approval, the FDA must determine that our or our third party contractor's manufacturing facilities meet current Good Manufacturing Practice ("GMP") requirements before we can use them in the commercial manufacture of our products. We and all of our contract manufacturers are required to comply with the applicable current GMP regulations. Manufacturers of biologics must also comply with the FDA's general biological product standards. In addition, GMP regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation sufficient to ensure the quality of the approved product. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as delay of approval, suspension of manufacturing, seizure of product or voluntary recall of a product***.

81. The 1Q 2012 Form 10-Q contained the following risk factors:

> We rely on our facility in Düsseldorf, Germany and third parties to supply materials necessary to manufacture our product candidates. We have limited experience in manufacturing sufficient quantities of ISS for our commercial products and rely on limited third parties to produce the ISS we will require for commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities.
>
> We rely on a number of third parties for the multiple steps involved in the manufacturing process of our product candidates, including ISS, the production of certain antigens, the combination of the antigens and ISS, and the fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development efforts.

> We have relied on a limited number of suppliers to produce ISS for clinical trials and a single supplier to produce our 1018 ISS for HEPLISAV. To date, we have manufactured only small quantities of ISS and 1018 ISS ourselves for development purposes. If we were unable to maintain our existing source for 1018 ISS, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing our product candidates, particularly HEPLISAV. We or other third parties may not be able to produce 1018 ISS at a cost, quantity and quality that are available from our current third-party supplier.
>
> ***We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process that must be performed in compliance with current GMP regulations***. We may not be able to comply with these and comparable foreign regulations, and our manufacturing process may be subject to delays, disruptions or quality control/quality assurance problems. ***Noncompliance with these regulations or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates and could result in significant expense.***

82. With respect to ongoing inspection and regulation of the Company's manufacturing facility following approval of the BLA, the 1Q 2012 Form 10-Q contained the following risk factors:

> If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review.
>
> ***We and our third party suppliers are required to comply with applicable current GMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities***. Suppliers of key components and materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, ***these third parties and our manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates***. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.
>
> ***If, as a result of their inspections, the FDA determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may not approve the product or may suspend the manufacturing operations.*** If the manufacturing operations of any of the suppliers for our product candidates are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies

> of product to meet market demand, which would harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we might be unable to ship our approved product for commercial supply or to supply our products in development for clinical trials. Significant and costly delays can occur if the qualification of a new supplier is required.
>
> Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or commercial use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.
>
> ***Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price***.

83. Defendants' statements in ¶¶ 79-82 were materially false and misleading when made. Defendants knew and/or recklessly disregarded, and failed to disclose, the following:

(a) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements; and

(b) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements.

84. Moreover, the 1Q 2012 Form 10-Q was signed by defendant Dina, and also contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") stating that "the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934" and "the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company." Defendant Dina further signed a separate certification, stating, in relevant part:

> 1. I have reviewed this Quarterly Report on Form 10-Q of Dynavax Technologies Corporation;

2. ***Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report***;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods present in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the Company's supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the Company's supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principals;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the Company's conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financing reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on the Company's most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involved management or other employees who have a significant role in the registrant's internal control over financial reporting.

85. Defendant Dina's statements in ¶ 84 were materially false and misleading when made because defendant Dina knew and/or recklessly disregarded, and failed to disclose the following:

(a) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements;

(b) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements.

86. On May 8, 2012 Dynavax issued a press release entitled "Dynavax Embarks on Transition to Commercialization," which stated in relevant part:

> Dynavax Technologies Corporation announced today, that following the recent submission of the U.S. Biologics License Application (BLA) to the Food and Drug Administration (FDA), it intends to begin developing a commercial operation capable of independently launching HEPLISAV™ in the U.S. The Company believes that being able to bring HEPLISAV to the market successfully will ultimately help maximize long-term value for its shareholders.
>
> With the goal of laying the foundation for long-term success, Dynavax plans to strengthen its senior team with the addition of experienced commercial leadership. Subsequent to a recommendation from Dino Dina, the Company's Chief Executive Officer, the Company's Board of Directors has agreed to initiate a process that they anticipate will include his succession. Dr. Dina plans to continue in his role as CEO through this process and will support the transition to his eventual successor. He will also continue as a member of the Company's Board thereafter.
>
> Dr. Dina joined Dynavax in May 1997 and has led the transformation of the Company from its early days through the research and development phase. Said Dr. Dina, "I believe now is the right time to prepare Dynavax to effectively capitalize on the significant market opportunity we have ahead of us when we are able to bring the benefits of HEPLISAV to the public. I am committed to working with our Board to plan for the success of Dynavax."
>
> "Dino's leadership and vision have been critical in making Dynavax what it is today, a diversified company with an important product candidate in HEPLISAV

> and a maturing pipeline. We fully endorse the strategic direction for Dynavax that Dino has set and appreciate Dino's commitment to a smooth and seamless transition process," said Arnold Oronsky, Ph.D., Chairman of the Board. "We are confident that Dino and the leadership team will remain focused on Dynavax's success and building value for shareholders in the years ahead."

87. On May 9, 2012 Dynavax issued a press release announcing the pricing of a public offering of 17.5 million shares of its common stock at $4.25 per share. The release stated in part:

> Dynavax Technologies Corporation today announced the pricing of an underwritten public offering of 17,500,000 shares of its common stock, offered at a price to the public of $4.25 per share. The gross proceeds to Dynavax from this offering are expected to be approximately $74.4 million, before deducting underwriting discounts and commissions and other offering expenses payable by Dynavax. Dynavax has granted the underwriters a 30-day option to purchase up to an aggregate of 2,625,000 additional shares of common stock to cover over-allotments, if any. All of the shares in the offering are to be sold by Dynavax. The offering is expected to close on or about May 14, 2012, subject to customary closing conditions. Dynavax expects to use the net proceeds from the offering primarily to fund activities in preparation for the anticipated commercial launch of HEPLISAV™, subject to receipt of regulatory approval, including the manufacture of commercial supply, to fund the marketing, sales and medical affairs infrastructure and personnel, including the hiring of a field sales force, and to commercialize HEPLISAV in the United States, if approved by the U.S. Food and Drug Administration, as well as for other general corporate purposes.

88. Also on May 9, 2012, the Company filed with the SEC two prospectus supplements in connection with the offering pursuant to Rule 424(b)(5), one supplementing a prospectus dated October 6, 2010, signed by each of the Individual Defendants, and the other supplementing a prospectus dated July 22, 2011, also signed by each of the Individual Defendants. Both prospectus supplements incorporated by reference the 1Q 2012 Form 10-Q, as well as the Annual Report on Form 10-K for the year ended December 31, 2011, which was filed with the SEC on March 12, 2012 and signed by each of the Individual Defendants. Both prospectus supplements expressly incorporated by reference the risk factors from the 1Q 2012 Form 10-Q, including those set forth in ¶¶ 80–82 above.

89. On June 26, 2012, Dynavax issued a press release announcing the FDA's acceptance of the Company's BLA for HEPLISAV, pursuing an indication for immunization

against infection caused by all known subtypes of hepatitis B virus in adults 18 through 70 years of age. The press release stated in part:

> Dynavax Technologies Corporation today announced that the Food and Drug Administration (FDA) has accepted for review the U.S. Biologics License Application (BLA) for HEPLISAV, pursuing an indication for immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 through 70 years of age.
>
> Dynavax President and Chief Medical Officer, Tyler Martin, M.D., said, "***The FDA has established February 24, 2013, as the PDUFA action date. We look forward to working with the FDA in moving HEPLISAV through the regulatory review process over the next few months***."
>
> The Company anticipates submitting a European Marketing Authorization Application (MAA) for HEPLISAV in the third quarter of 2012. Upon approval of the HEPLISAV BLA, Dynavax plans to submit a supplemental BLA for an indication in patients with chronic kidney disease.

90. Moreover, during a July 12, 2012 JMP Securities Healthcare Conference, defendant Martin reiterated his optimism regarding the Company's transition to commercialization of HEPLISAV. Defendant Martin stated, in pertinent part:

> ***So we submitted the BLA in April. The filing was accepted in June. We have a PDUFA date of February***. Our MAA submission is on track; we expect to submit it in this quarter. ***As a result of the PDUFA date, we expect to launch in Q2 in the US, based on our anticipated FDA approval at the PDUFA date***.
>
> We're developing a strategy for commercialization. Some of you may have seen it. Just last week we announced that we have hired a VP of Global Sales and Marketing. His name is David Happel. I've worked with him at previous companies. He has effectively, on two previous gigs of his, launched products in the biotechnology space. So he's used to launching products in our resource environment, where we have to be focused on how we're going to deliver value without the resources that a large pharmaceutical company has.

91. Defendants' statements in ¶¶ 88-90 were materially false and misleading when made. Defendants knew and/or recklessly disregarded, and failed to disclose, the following:

(a) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements; and

(b) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the

Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements.

92. On August 3, 2012, Dynavax filed its Form 10-Q for the quarter ending June 30, 2012 (the "2Q 2012 Form 10-Q"), signed and certified by defendant Dina. In regard to HEPLISAV, the BLA submission, and the Company's business, operations, and prospects, the 2Q 2012 Form 10-Q stated, in relevant part:

> In June 2012, we reported that the FDA has established February 24, 2013 as the PDUFA action date for HEPLISAV's BLA, pursuing an indication for immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 through 70 years of age. In July 2012, we submitted a Marketing Authorization Application for HEPLISAV to the European Medicines Agency for an indication in adults 18 through 70 years of age and in patients with chronic kidney disease. Upon approval of the HEPLISAV BLA, we plan to submit a supplemental BLA with an indication and 3-dose primary vaccination regimen for patients with chronic kidney disease.

93. In regard to process validation program and manufacturing controls specifically, the 2Q 2012 Form 10-Q contained identical risk factors as the 1Q 2012 Form 10-Q, set forth in ¶¶ 80–82, preceding.

94. Defendants' statements in ¶¶ 92–93 were materially false and misleading when made. Defendants knew and/or recklessly disregarded, and failed to disclose, the following:

(a) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements; and

(b) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements.

95. Moreover, the 2Q 2012 Form 10-Q contained a SOX certification signed by defendant Dina, as well as a separate certification containing the same form and content as the 1Q 2012 Form 10-Q, set forth in ¶ 84, preceding, except for the period of the report. Defendant

Dina's statements contained therein were materially false and misleading when made because defendant Dina knew and/or recklessly disregarded, and failed to disclose, the following:

(a) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements; and

(b) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements.

96. Between August 16 and 23, 2012, the FDA conducted the inspection of the Company's Dusseldorf facility, resulting in the issuance of the Form 483 identifying twenty-seven different significant objectionable conditions, as detailed in ¶¶ 64–67 above.

97. At no point thereafter did Defendants update or correct their prior statements concerning (i) the requirement that Dynavax pass a preapproval inspection of its manufacturing facilities (¶¶ 80–82, 88, 93, 103); (ii) Dynavax's ongoing work with the FDA to obtain approval of the BLA (¶ 76); and (iii) Dynavax's expectation that it would launch HEPLISAV commercially in the U.S. in the second quarter of 2013 (¶ 90).

98. On August 28, 2012, Dynavax issued a press release announcing that the FDA Advisory Committee was commencing review of HEPLISAV. The press release stated in part:

> Dynavax Technologies Corporation today announced that the U.S. Food and Drug Administration (FDA) has informed the Company that its Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to discuss HEPLISAV at its meeting on November 14-15, 2012. Dynavax's Biologic License Application (BLA) for HEPLISAV, pursuing an indication for immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 through 70 years of age, is currently under review by the FDA. The Prescription Drug User Fee Act (PDUFA) date for the FDA to complete its review is February 24, 2013.
>
> "The VRBPAC meeting is the next step toward bringing HEPLISAV to physicians and patients," said Dynavax President and Chief Medical Officer, Tyler Martin, M.D. "***Our team*** looks forward to discussing HEPLISAV with the advisory committee and ***will continue to work closely with the FDA through the review process***."

About Vaccines and Related Biological Products Advisory Committee

VRBPAC reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases.

99. Defendants' statements in ¶ 98 were materially false and misleading when made. Defendants knew and/or recklessly disregarded, and failed to disclose, the following:

(a) Dynavax's Dusseldorf manufacturing facility failed its pre-approval inspection;

(b) Following the pre-approval inspection of the Dusseldorf manufacturing facility a Form 483 was issued identifying twenty-seven different significant objectionable conditions;

(c) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements; and

(d) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements.

100. Confirming the misleading nature of Dynavax management's statements pertaining to HEPLISAV's BLA, equity analysts continued to report positive outlook for the chances of approval for the BLA. For example, an October 8, 2012 Cowen and Company analyst report stated:

On Thursday October 4 and Friday October 5, we hosted a number of investor meetings with Dynavax's CEO Dino Dina and CFO Cris Larson. The discussions were largely focused on Heplisav's November 15 FDA panel review, ***Dynavax's commercialization plans***, and Heplisav's intellectual property. We came away from the meetings confident that Dynavax has exhaustively analyzed Heplisav's database, and found no concerning safety signals that should prevent a positive panel vote. Our optimism that Heplisav will be recommended for approval on November 15 was therefore increased.

* * *

> Nonetheless, overall the company expects the day to focus on Heplisav's risks and benefits in adults ages 18-70, and therefore the FDA will seek the panel's input on whether Heplisav's pivotal studies support licensure. Management indicated that the approximate 5,000 patient program was designed with the input of the FDA, and the FDA had indicated that trials enrolling at least 3,850 patients in total would be appropriate to support a label for the vaccination of adults as long as the trials did not uncover an unanticipated risk.

101. On October 15, 2012, Dynavax stock was trading at $5.06 per share. The next day, October 16, 2012, while Dynavax common stock was trading between $4.96 and $4.67 per share, SCP LP, under the control of Kessel, SCP GP, and SGP LLC, sold 5,690,651 shares of Dynavax common stock for $4.72604 per share, generating gross proceeds of more than $26.8 million. The same day, SSP LLC, under the control of Kessel, sold 309,349 shares of Dynavax common stock for $4.72604 per share, generating gross proceeds of more than $1.4 million.

102. On November 1, 2012, Dynavax issued a press release announcing its third quarter 2012 financial results. The Company discussed its recent developments regarding HEPLISAV, and stated in part:

- In June 2012, we reported that the FDA has established February 24, 2013, as the Prescription Drug User Fee Act (PDUFA) action date for our HEPLISAV Biologics License Application, pursuing an indication for immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 through 70 years of age. In August 2012, the FDA informed the Company that its Vaccines and Related Biological Advisory Committee is scheduled to discuss HEPLISAV at its meeting on November 15, 2012.

- In July 2012, the American Medical Association Current Procedural Terminology (CPT) Panel established a CPT code for an adult two dose hepatitis B vaccination schedule. CPT codes are designed to communicate uniform information about medical services and procedures among physicians and payers for administrative and financial purposes. If approved, HEPLISAV will be reported using the new two dose code, differentiating it from a three dose hepatitis B vaccine schedule.

- In July 2012, we filed a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for HEPLISAV for use in adults 18 through 70 years of age and in patients with chronic kidney disease. The Company was subsequently notified in August 2012 by the EMA that its MAA was accepted for review. The EMA is a European Union agency responsible for the evaluation of medicinal products that allows companies to submit a single application for marketing authorization in all European Union and European Economic Area European Free Trade Association states.

103. On November 2, 2012, Dynavax filed its Form 10-Q for the quarter ending September 30, 2012 (the "3Q 2012 Form 10-Q"), signed and certified by defendant Dina, which contained the same recent developments regarding HEPLISAV as the November 1, 2012 press release. In regard to process validation program and manufacturing controls specifically, the 3Q 2012 Form 10-Q contained identical risk factors as the 1Q 2012 Form 10-Q, set forth in ¶¶ 80–82, preceding.

104. Defendants' statements in ¶ 103 were materially false and misleading when made. Defendants knew and/or recklessly disregarded, and failed to disclose, the following:

(a) Dynavax's Dusseldorf manufacturing facility failed its pre-approval inspection;

(b) Following the pre-approval inspection of the Dusseldorf manufacturing facility a Form 483 was issued identifying twenty-seven different significant objectionable conditions;

(c) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements; and

(d) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements.

105. Moreover, the 3Q 2012 Form 10-Q contained a SOX certification signed by defendant Dina, as well as a separate certification containing the same form and content as the 1Q 2012 Form 10-Q, set forth in ¶ 84, preceding, except for the period of the report. Defendant Dina's statements contained therein were materially false and misleading when made because defendant Dina knew and/or recklessly disregarded, and failed to disclose, the following:

(a) Dynavax's Dusseldorf manufacturing facility failed its pre-approval inspection;

(b) Following the pre-approval inspection of the Dusseldorf manufacturing facility a Form 483 was issued identifying twenty-seven different significant objectionable conditions;

(c) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements; and

(d) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements.

106. The VRBPAC discussed HEPLISAV and Dynavax's BLA at its meeting with the Company on November 14-15, 2012, wherein the overall weaknesses in the Company's BLA began to be disclosed to the investing public for the first time, as set forth in ¶¶ 68–70, *supra*. The Company also issued a press release on November 15, 2012 entitled "Dynavax Announces FDA Advisory Committee Meeting Outcome for HEPLISAV(TM)," stating, in relevant part:

> Dynavax Technologies Corporation today announced that the U.S. Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (Committee) voted 13 to one that HEPLISAV data adequately demonstrated immunogenicity. Additionally, the Committee voted eight to five with one abstention that there was insufficient data to adequately support the safety of HEPLISAV.
>
> Now that Dynavax has received the Committee's input and vote, ***the Company will continue working with the FDA as it completes its review of the HEPLISAV application***. The scheduled Prescription Drug User Fee Act (PDUFA) date for HEPLISAV is February 24, 2013.

107. Following the VRBPAC meeting, based upon Defendants' prior statements, analysts believed that even if Dynavax's BLA was rejected, HEPLISAV might be approved for a more narrowly defined population. The response of the analysts also demonstrates that they were unaware of the insufficient process validation program and manufacturing controls data submitted in the BLA, the failed pre-approval inspection of the Dusseldorf facility, and the

issuance of the Form 483 to Dynavax. For example, Y. Katherine Xu, an analyst with William Blair & Co., stated that even if the vaccine was not approved for adults aged 18 to 70:

> Second Best Case: FDA approves Heplisav with a restricted label to include only adults between 40 and 70 years of age, as there is a high unmet need in this higher risk population and a stronger benefit risk argument could be made for this population. In September 2009 when the FDA lifted the clinical hold off Heplisav, the agency asked Dynavax to study Heplisav in hyporesponsive populations such as adults over 40, and chronic kidney disease (CKD) patients. It was at the pre-BLA meeting earlier this year that the application of label was expanded from 40-70 years to 18-70 years. We believe if the agency balances the VRBPAC concerns with the stronger benefit-risk arguments in hyporesponsive populations, Heplisav could potentially garner approval in adults aged 40 to 70.
>
> * * *
>
> Another Case: obtain approval in CKD patients. The CKD patients represent perhaps the highest unmet need among various hyporesponsive populations. Dynavax currently has the Phase III Study HBV-17 data in hand in CKD patients and has been planning to submit that data to the FDA early next year in a supplemental BLA (sBLA). Together with the current BLA package, Dynavax might be able to argue for approval in this population should the best case or the second best case be denied by the FDA.

108. On February 25, 2013 Dynavax issued a press release announcing the Company's receipt of the CRL from the FDA regarding its BLA for HEPLISAV. Dynavax has failed to ever disclose the contents of the CRL. The Company press release regarding the CRL stated in relevant part:

> Dynavax Technologies Corporation announced today that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA or Agency) regarding its Biologic License Application (BLA) for HEPLISAV, an investigational adult hepatitis B vaccine.
>
> In the CRL, the FDA specified that the indication in adults 18-70 years of age cannot be approved without further evaluation of safety in this broad age group. The FDA also continues to express concern that novel adjuvants may cause rare autoimmune events. However, the Agency indicated its willingness to continue discussions regarding a more restricted use of HEPLISAV. Dynavax plans to discuss the CRL with the FDA to identify the most expeditious path to approval for HEPLISAV, particularly in adults who may receive the greatest benefit from HEPLISAV.
>
> ***Furthermore, the FDA requested additional data from Dynavax's process validation program and clarifying information on the manufacturing controls and facilities related to the assurance of the quality of the commercial product. Dynavax believes it can provide the information but the exact timeframe for its response cannot be determined until it has met with the Agency.***

> Dynavax plans to meet with the FDA to discuss the steps necessary for potential approval of HEPLISAV and currently believes the meeting can take place within 6 weeks. Following its meeting with the FDA, Dynavax will provide updates as appropriate.

109. Following the issuance of the CRL, Thomas Wei, an analyst with Jeffries, issued a report on February 25, 2013 stating that the manufacturing and controls issues and Dynavax's failure to present existing safety data for CKD subjects came as a surprise to analysts. The report stated, in relevant part:

> **What's New In The CRL: Manufacturing Issues Are The Surprise.**
>
> In the CRL, the FDA asked for more safety data to support the broad indication of healthy adults 18-70 due to the hypothetical risk of rare autoimmune adverse events. This was in line with the panel vote and our analysis last week. We are disappointed that the FDA is not more explicit in its requirements, but DVAX expects this to be a focus topic at the next meeting with the FDA. Encouragingly, the FDA signaled a willingness to consider Heplisav for a focused use. We believe the most viable options are a label restricted to chronic kidney disease (CKD) patients, adults over 40, or both of these. Although the FDA had a preliminary study report for the Phase 3 trial in CKD and had the ability to analyze all of the current efficacy and safety data for over 40, DVAX confirmed that it had never submitted formal analyses of data for either subpopulation, and we do not believe that the FDA has reviewed the data for either of these restricted populations in a rigorous way. ***In a negative surprise, the CRL also contains questions related to manufacturing (process validation and controls).***

110. Despite receiving the CRL rejecting HEPLISAV's BLA, the Company continued to express confidence that the FDA would approve a more restricted use of HEPLISAV. On the same day, February 25, 2013, Dynavax held a conference call with investors, analysts, and the media to discuss the FDA's CRL regarding the BLA for HEPLISAV, during which defendant Dina expressed unfounded confidence that HEPLISAV could still be approved under a more focused label without submitting additional safety data to the FDA. Moreover, Dina admitted that there was nothing in the CRL regarding the manufacturing CMC that surprised Defendants. Specifically, defendant Dina stated the following:

> [DINA:] However, we believe the door remains open for a more-focused label for HEPLISAV with the safety data that we currently have.
>
> Specifically, FDA has expressed their willingness and interest in continuing the discussion about what information is needed to support a more focused use of HEPLISAV, stating that the safety data required for its licensure will depend on

the indication of HEPLISAV and a favorable risk-benefit determination associated with that specific indication.

We will request a meeting with the FDA to discuss the CRL, and we believe the meeting can take place within the next six weeks. Our task is to gain a better understanding of the specific issues and implement plans to address them. We intend to seek a path forward towards approval in a more-focused population, which may be achievable without an additional clinical study. And this may include, once we gain clarity from FDA, pursuit of the chronic-kidney-disease population, adults over age of 40, and other groups who have not responded well to currently available HPV vaccines where HEPLISAV has been shown to provide significant benefit.

* * *

Furthermore, FDA has asked us to provide additional data from our process-validation program and to clarify information on our manufacturing controls and facilities related to the assurance of the quality of the commercial product. We believe this information is addressable, but until we meet with the agency, it is difficult to make any predictions about the exact timeframe for our response.

* * *

[ANALYST]: Okay. And so, is the – when we think about the next pathway here, is it – should we think that the most viable strategy would be CKD or is it the fact that most of your data is in adults over 40 or could you actually file for both or would you propose maybe filing for two separate indications together of CKD and adults over 40?

[DINA]: Well, all of those options are possible and available. It's just a matter now of reaching agreement with FDA about what's the most expedient and what they're willing to consider. We don't have any indications from them, so far, of where their mind is in terms of what would be appropriate and what they're willing to work with us on.

However, it would seem that CKD would be something that they would be willing to consider and that any indication for a population over-40 would certainly fit the definition of a population that would receive increased benefit.

* * *

[Analyst]: And then just something on manufacturing, I guess I'm a little bit confused here, maybe just to get some clarity. Do you think – is this going to require you making new HEPLISAV in running studies on new batches? And can you also say whether or not the manufacturing comments from the FDA impacts at all the process in Europe and the approvability of manufacturing there?

[DINA]: ***Let me separate those two questions and make sure I understood your first question correctly. If you're asking whether we would be required to do additional clinical studies, I think that the answer is that based on our reading of the Letter, that's clearly not the case. There may be some limited additional amount of work that we may have to do at our facilities to provide all the data that have been requested but it's all with them, our ability to manufacture and produce the surface antigen and the final product***.

> With respect to the – your second point, let me remind you that we are currently licensed for commercial production of surface antigen in Europe. What remains to be done and finished is to obtain a license for the final product which contains ISS 1018 which is made in the U.S. and so that's the piece that we're going to have to complete European approval to be able to sell the product.
>
> * * *
>
> [Analyst]: Good morning, guys. Thanks for taking the question. Dino, I just wanted to follow up with the last question on manufacturing. The first one was, were any issues that manufacturing has surprised you in the CRL because you have been talking to the FDA since November. And then maybe, can you address what data you've already generated to address the manufacturing questions in the CRL? And I have a follow-up.
>
> [DINA]: ***I don't believe that there were any surprises***. There were a number of iterations, and so we might have been slightly disappointed. ***We were asked – being asked questions that we had already answered***. But I think that that's part of the process and how we've ended up with an interrupted BLA review after the RBPAC meeting. ***So, there was nothing that was shocking or we had not anticipated in the CMC questions.***
>
> With respect to the second part of your question, let me pass and not go into of the any details that relate to that because I don't think that would be appropriate at this time.

111. On this news, shares of Dynavax declined $0.96 per share, or 32%, to close on February 25, 2013 at $2.01 per share, on unusually heavy volume.

112. Following the conference call, despite the CRL, analysts believed Defendants' representations that HEPLISAV could still be approved by the FDA based upon existing data Dynavax failed to include in the BLA. For example, on March 4, 2013 following the conference call, Phil Nadeau, an analyst with Cowen and Company, stated:

> We believe that the language in the CRL suggests that the FDA is prepared to seriously consider approving Heplisav with a restricted label after the submission of a modest amount of new data (perhaps even just the CKD Phase III's that have been completed). Dynavax is entitled to a meeting with the FDA within 6 weeks. We suspect that the negotiations between FDA and DVAX will take several months, and therefore more clarity is unlikely before Q2 or mid-2013.

113. Moreover, on a March 5, 2013 conference call with investors, analysts, and the media, defendant Dina once again underscored the potential for HEPLISAV's restricted indication approval without submitting additional safety data even in light of the manufacturing issues raised by the CRL, stating:

> So where we are today is that as you know we received a CRL a week ago, and we need to essentially get back in front of FDA to define what is the approval path. ***FDA left the door completely open for an approval for a restricted indication for the vaccine, while we accumulate more safety data for a broad indication***. And then we need to continue, of course, the path towards approval for the vaccine in Europe, which is proceeding according to plan. We are doing all work to analyze and prepare our response to the complete response letter. As I said, there are a number of issues that need to be clarified. ***And in particular, what kind of indication FDA would be prepared to accept without additional data, remains an open-ended question***.
>
> * * *
>
> ***We need to finish providing FDA with the data that they've requested with respect to manufacturing. Let me point out that there were no questions or challenges to our plant for having a manufacturing process per se***.
>
> ***What FDA has requested is additional data that support our validation [indiscernible] procedures and those are either available or can be obtained in the immediate future***. And we are working very solidly on responding to the day 120 questions from Europe. ***And let me reiterate the fact that we saw no [indiscernible] stoppers in those questions. We believe we can answer them satisfactorily. And we're proceeding with that***.

114. On March 8, 2013, Dynavax filed its Annual Report on Form 10-K for 2012, which was signed by each of the Individual Defendants. This Form 10-K continued to represent the potential for HEPLISAV's restricted indication approval, stating:

> On February 25, 2013, Dynavax announced that it had received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA" or "Agency") regarding its Biologic License Application ("BLA") for HEPLISAV. In the CRL, the FDA specified that the indication in adults 18-70 years of age cannot be approved without further evaluation of safety in this broad age group. The FDA also expressed concern that novel adjuvants may cause rare autoimmune events, however, ***the Agency indicated its willingness to continue discussions with us regarding a more restricted use of HEPLISAV.***

115. Defendants' statements in ¶¶ 108, 110, 113–114 were materially false and misleading when made. Defendants knew and/or recklessly disregarded, and failed to disclose, the following:

(a) Dynavax's Dusseldorf manufacturing facility failed its pre-approval inspection;

(b) Following the pre-approval inspection of the Dusseldorf manufacturing facility a Form 483 was issued identifying twenty-seven different significant objectionable conditions;

(c) At the time the BLA was submitted, Dynavax had not properly validated its manufacturing processes to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements; and

(d) Dynavax and its BLA lacked sufficient data to demonstrate that the Company had validated its manufacturing processes and controls to ensure that the Company could consistently manufacture HEPLISAV vaccines that meet FDA requirements; and

(e) That based on communications with the FDA after the receipt of the CRL on February 25, 2013, Defendants lacked any reasonable basis for their positive statements about HEPLISAV's approval, even on a "restricted label" basis.

116. In the aftermath of the failed BLA, on April 30, 2013, Dynavax announced the appointment of Eddie Gray as a Board member and CEO, replacing defendant Dina, and the "departure" of defendant Martin as President and CMO, all effective May 1, 2013.

117. On May 6, 2013, the Company issued a press release announcing its financial results for the first quarter of 2013. Notably, in the wake of the failed BLA, the press release announced an increase of $1.2 million in research and development costs and $3.0 million in general and administrative expenses, attributing both largely to "severance expenses, including non-cash stock-based compensation charges."

Dynavax Finally Comes Clean About The Future Of The HEPLISAV BLA

118. Then, on June 10, 2013 the Company issued a press release entitled "Dynavax Reports Feedback From FDA Meeting Regarding HEPLISAV(TM) Biologic License Application." Therein, the Company stated, in relevant part:

> Dynavax Technologies Corporation today reported that it recently concluded a meeting with the U.S. Food and Drug Administration (FDA or Agency) regarding its Biologic License Application (BLA) for HEPLISAV, an investigational adult

hepatitis B vaccine. The meeting followed recommendations expressed in November 2012 by the Vaccines and Related Biological Products Advisory Committee (VRBPAC) regarding the size of Dynavax's safety database. The meeting with FDA resulted in the following messages:

- The safety database does indeed need additional subjects;
- VRBPAC's strong endorsement of HEPLISAV's demonstrated immunogenicity was acknowledged;
- Analyzing the benefit/risk of HEPLISAV's use in discrete patient populations did not fundamentally address the shortfall in the safety database. It was concluded that to do so would unnecessarily restrict the patient population that could benefit from HEPLISAV's approval;
- The additional safety data collected would facilitate review for an indication in adults 18-70 years of age.

"We are encouraged by the supportive feedback received from the FDA and appreciate the informative interactions and clarity provided regarding HEPLISAV's path toward approval in the broader indication," commented Eddie Gray, Dynavax's Chief Executive Officer. "We understand the rationale for the Agency's recommendations and will give full consideration to their feasibility and timing as we advance HEPLISAV's development."

Dynavax will meet with the FDA shortly to discuss the protocol for collecting the additional safety data, which is expected to be incorporated into the existing BLA. ***The Company also continues to work on the questions raised by the FDA in the Complete Response Letter (CRL) regarding the manufacturing and testing of HEPLISAV***. Dynavax will provide updates as appropriate.

119. On a special conference call on June 10, 2013, Dynavax's new CEO, Eddie Gray, stated that the result of the FDA's findings ***were not surprising to the Company***, despite the prior confidence. Specifically, Gray stated:

> ***In my view, the outcome of the meeting was clear and followed, I think, predictably the themes expressed by VRBPAC last November.*** As we disclosed in the press release issued today, the main conclusions can be summarized as follows.
>
> Firstly, there was a strong endorsement for HEPLISAV's immunogenicity data demonstrated in previous clinical trials. In that context, the spirits and the tone of the interactions with the FDA suggest to us of their support for HEPLISAV's path forward to approval.
>
> Secondly, there was an acknowledgment that our safety database needs additional patients to support approval for any indication. Because HEPLISAV contains a novel adjuvant, we will need to increase the number of patients valuable for safety.
>
> Although we did discuss with FDA HEPLISAV's use in discrete patient populations, focusing on the improved benefit risk profile of the product in these

> groups, this approach did not address the fundamental issue of a shortfall in the safety database. Furthermore, our discussions suggest this would have necessarily restrict the patient population that could benefit from HEPLISAV's approval.

120. On this news, Dynavax stock declined $1.07 per share, or 43.32%, to close on June 10, 2013 at $1.40 per share, on unusually heavy volume.

POST CLASS PERIOD EVENTS

121. On October 16, 2013 Dynavax issued a press release announcing study HBV-23, its next Phase III clinical trial for HEPLISAV. According to the press release "[i]t will be an ***8,000 subject***, Phase 3, observer-blinded, randomized, active-controlled, multicenter trial of the safety and immunogenicity of HEPLISAV compared with Engerix-B® in adults 18 to 70 years of age." The primary objectives of HBV-23 will be (1) to evaluate the overall safety of HEPLISAV with respect to clinically significant adverse events; and (2) to demonstrate the noninferiority of the peak seroprotection rate (SPR) induced by HEPLISAV to Engerix-B in subjects with type 2 diabetes mellitus. The Company further announced that the study would generate external costs alone in the range of $50-55 million.

122. Then, on October 25, 2013, Dynavax issued a press release pricing two separate underwritten offerings of (1) 79,570,000 shares of its common stock at a price to the public of $1.075, for expected gross proceeds of $85.5 million and (2) 43,430 shares of its Series B Convertible Preferred Stock ("Series B") at a price to the public of $1,075.00, for expected gross proceeds of $46.7 million. Dynavax stated that the proceeds would be used "to fund development activities associated with conducting an additional Phase 3 study of HEPLISAV™ and seeking regulatory approval to commercialize the vaccine in the United States and Europe, and for other general corporate purposes, including working capital."

ADDITIONAL SCIENTER ALLEGATIONS

123. As alleged herein, Defendants acted with scienter because at the time that they issued public documents and made other public statements in Dynavax's name, they knew or recklessly disregarded the fact that such statements were materially false and misleading and/or omitted material facts concerning the failures of the Company's process validation program and

manufacturing controls at the facilities related to the assurance of the quality of the commercial product for HEPLISAV, and the prospects for FDA approval of HEPLISAV's BLA in light of the omissions of material data in the BLA. Defendants (1) knew that such documents and statements would be issued or disseminated to the investing public, (2) knew that persons were likely to rely upon those misrepresentations and omissions, and (3) knowingly and/or recklessly participated in the issuance and/or dissemination of such statements and/or documents as primary violators of the federal securities laws. Defendants' materially false and misleading statements and omissions of material fact artificially inflated Dynavax's stock price during the Class Period.

The Individual Defendants

124. Because the fraud alleged herein relates to the core business of Dynavax, knowledge of the facts underlying the fraudulent scheme may be imputed to the Individual Defendants. Indeed, HEPLISAV was the Company's "lead product candidate," and therefore the Individual Defendants, as senior level executives and/or directors, were in such positions at the Company to access all material, non-public information concerning the structure of the clinical trials, the actual results of those trials on a real-time basis, and the material information submitted to the FDA within the BLA. Thus, the Individual Defendants were well-aware that the positive statements detailed above about HEPLISAV and the BLA, made contemporaneously with knowledge of contradictory information, were materially false and/or misleading when made.

125. In fact, according to CW6, immediately after the Form 483 was given to Rhein Biotech CEO Zbigniew Janowicz on-site at the close of the inspection in August 2012, Janowicz then would have directly reported the results of the Form 483 directly to Defendants Dina and Martin.

126. Moreover, each of the Individual Defendants were highly educated, trained, and experienced in vaccine and drug development, clinical trials, and the preparation and submission of BLA's to the FDA for licensing and approval of biologics. For example, Defendant Dina received his M.D. from the University of Genoa Medical School in Italy. Dina was a founder of

the Company and has been a member of the Board since May 1997 and CEO since May 1998. Dina is the author or co-author of at least six scholarly articles on the subjects of biophysics, cell biology, and genetics. From May 1997 to June 2010, Dina was also president of Dynavax. From 1982 until founding Dynavax in 1997, Dina was an employee of Chiron Corporation, a pharmaceutical company, where he held a number of positions with increasing responsibility. Ultimately, Dina served as president of Chiron Vaccines (formerly Biocine Company), which he directed from its inception in 1987. Under Dina's direction, Chiron Vaccines received the first-ever approval of an adjuvanted influenza vaccine in Italy, successfully completed development of the first genetically engineered pertussis vaccine and conducted clinical trials for vaccines to prevent HIV, herpes simplex type II, cytomegalovirus, and hepatitis B infections. The virology group he directed at Chiron was responsible for several key scientific findings, including the discovery, cloning, and sequencing of the hepatitis C virus, and the cloning and sequencing of the viral genomes for HIV and hepatitis A viruses. Prior to joining Chiron, Dina was employed at Albert Einstein College of Medicine in Bronx, New York, as an assistant professor of genetics from 1977 to 1982.

127. Dina has or has submitted applications for more than 7 patents for biologics which serve as immunostimulatory or immunomodulatory agents for which Dina is listed as the inventor, including second-generation TLR9 agonists related to ISS 1018. Consequently, one CW has stated that Dina viewed HEPLISAV as his "baby."

128. Defendant Martin received a B.S. in Chemistry and an M.D. from the University of Nebraska. Martin completed his fellowship in pediatric infectious diseases and molecular microbiology at Washington University in St. Louis, Missouri. As further detailed below, Martin is the author or co-author of numerous scholarly articles on immunology, adjuvants and the HEPLISAV clinical trials. Martin joined Dynavax as CMO in 2009. In 2010 Martin was promoted to President and became a member of the Board. In conjunction with the promotion to President, the Board appointed a committee consisting of defendant Kessel and Board member Francis Cano to advise Dina and Martin in the delegation of duties from Dina to Martin and the

transition to leadership of the Company by Martin. On November 12, 2010 Martin entered into a Management Continuity and Severance Agreement which provided financial incentives to Martin to remain with the Company during this transition in leadership. Along with the promotion, Martin received a $50,000 increase in base salary and an award of options to purchase 517,244 shares of common stock at $1.72 per share. Then in October 2012, after the submission of the knowingly deficient BLA and just one month before the VRBPAC meeting to determine the fate of HEPLISAV, the Company announced that it was looking for a new outside CEO and amended and restated Martin's Management Continuity and Severance Agreement to provide for the terms on which Martin would ultimately leave the Company, rather than become its new CEO.

129. Martin was involved in the day-to-day operations of Dynavax and had a hands-on role in the Company's clinical trials and the preparation of the BLA for HEPLISAV. Or as described by CW1, Martin's "finger was on the pulse" of the study DV2-HBV-16 and he knew the study like he was running it. Martin was also the co-author of "Comparison of safety and immunogenicity of two doses of investigational hepatitis B virus surface antigen co-administered with an immunostimulatory phosphorothioate oligodeoxyribonucleotide and three doses of a licensed hepatitis B vaccine in healthy adults 18-55 years of age," ("Comparison") published at Vaccine 30 (2012) 2556- 2563. Comparison was an analysis of study DV2-HBV-10.

130. Further, Martin was actively involved in responding to and communicating with the FDA with regards to the HEPLISAV BLA. Moreover, CW2 stated that Martin was aggressive in pursuing FDA approval of the vaccine and established a timeline for compiling and submitting the BLA which other Company employees said were "crazy" and unrealistic. CW2 further stated Martin received "pre-packets" from various Dynavax direct reports, which were early compilations of data for the BLA submission, which he reviewed meticulously, giving him an intimate knowledge of the BLA and the data submitted in support thereof. Moreover, the VP of Regulatory Affairs Bill Turner, who was present during the inspection at the Dusseldorf facility in August 2012, and VP of Clinical Development William Heyward, reported directly to

Martin and met with him frequently to discuss the status of the BLA. In addition, the VP of Clinical Operations Lani Ibarra, former Senior Director of Clinical Development (and current CMO) Robert Janssen, Edie Smith (project management), former Chief Commercial Officer Brant Biehn, and General Counsel Michael Ostrach met with Martin frequently to discuss the BLA.

131. In addition, the Individual Defendants were further motivated to conceal Dynavax's tenuous chances of achieving FDA approval and the true extent of the insufficient BLA because the Company was continuously reliant upon securities offerings to the capital markets to implement its business strategy and planned product development efforts. These offerings would have been negatively impacted if the truth about the Company's tenuous chances of achieving FDA approval and the true extent of the insufficient BLA were actually disclosed. Therefore, maintaining an inflated stock price at the time of the offerings was essential to Dynavax's ability to maximize the ability to raise the capital it needed to fund its development efforts, commercialization and marketing activities for HEPLISAV.

Kessel And The Symphony-Related Entities

132. Pursuant to the Amended And Restated Purchase Option Agreement ("Amendment") between the Symphony-related entities and Dynavax in 2009, so long as the Symphony-related entities owned 10% or more of the Company's outstanding stock, the Symphony-related entities had the right to appoint one member of the Dynavax Board pursuant to which Kessel was appointed to his position on the Board to monitor the Symphony-related entities' interests in the Company. Moreover, the Amendment extended the existing obligation to pay the $15 million note owing to the Symphony related entities for the repurchase of hepatitis B drug candidates (such as HEPLISAV) until December, 2012 and Dynavax was given the option—at its sole discretion—to repay the obligation in cash or stock. This put pressure on Dynavax and the Individual Defendants to seek FDA approval of HEPLISAV before December 2012, to increase the trading price of Company stock to be used as currency to repay the obligation. In addition, Kessel, SCP GP, and SGP LLC, by virtue of their positions as managing

member and/or general partner of SCP LP and/or SSP LLC owed a fiduciary duty to SCP LP and/or SSP LLC and their respective limited partners and non-managing members. These fiduciary duties included the duty to be fully informed prior to selling the Dynavax common stock held by SCP LP and/or SSP LLC.

133. Prior to the Class Period, Kessel, SCP LP, SSP LLC, SCP GP, and SGP LLC were deemed to own 8,340,800 shares of Dynavax common stock, and Defendant Kessel was deemed to own an additional 20,000 shares. As a result of the May 2012 Offering, to comply with the anti-dilution provisions of the November 2009 amended financing agreement with the Symphony Defendants, the Company was required to issue SCP LP an additional 655,023 shares of Dynavax common stock and an additional 66,160 shares to SSP LLC, bringing the total number of Dynavax shares deemed owned by Kessel, SCP LP, SSP LLC, SCP GP, and SGP LLC to 9,031,431. With access to the Company's financial and corporate records, including the Form 483, on October 16, 2012—less than one month before the VRBPAC met to discuss HEPLISAV—SCP LP and SSP LLC, while under the control of Kessel, SCP GP and SGP LLC, collectively sold 6 million shares of Dynavax common stock for $4.72604 per share, or total proceeds of $28.36 million, leaving Kessel, SCP LP, SSP LLC, SCP GP, and SGP LLC deemed to own just 3,031,431 shares of Dynavax stock. This sale was highly unusual as to the amount of shares sold, the percentage of shares sold, the timing of the sale, and the prior trading pattern for Kessel, SCP LP, SSP LLC, SCP GP, and SGP LLC. This sale represented 66.4% of the Dynavax shares deemed owned by Kessel, SCP LP, SSP LLC, SCP GP, and SGP LLC at the time of the sale. Moreover, it reduced Kessel, SCP LP, SSP LLC, SCP GP, and SGP LLC's holdings of the Company below 10%, divesting them of the ability to designate a director of the Company. The sale also took place just six weeks after the issuance of the Form 483 and less than one month before the meeting of the VRBPAC. Finally, neither Kessel, SCP LP, SSP LLC, SCP GP, nor SGP LLC had ever sold shares of Dynavax common stock previously.

LOSS CAUSATION

134. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated Dynavax's stock price and operated as a fraud or deceit on Class Period purchasers of Dynavax stock by misrepresenting the Company's business and prospects. During the Class Period, Defendants misrepresented and concealed the failures of the process validation program and manufacturing controls at the facilities related to the assurance of the quality of the commercial product for HEPLISAV, and the prospects for FDA approval of HEPLISAV's BLA. Later, however, as Defendants' prior misrepresentations and omissions were disclosed and became apparent to the market, the price of Dynavax stock fell precipitously. As a result of their purchases of Dynavax stock during the Class Period at artificially inflated prices, Plaintiffs and other Class Members suffered damages as the truth regarding Dynavax's fraud was revealed.

135. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the damages suffered by Plaintiffs and the Class.

136. Defendants' false and misleading statements and omissions in their SEC filings and other public statements during the Class Period directly caused losses to Plaintiffs and the Class. On the strength of these false statements, the Company's stock price was artificially inflated to a Class Period high of $5.26 per share on May 2, 2012. Those misrepresentations and omissions that were not immediately followed by an upward movement in the Company's stock price served to maintain the share price at artificially inflated levels by maintaining and supporting a false positive perception of Dynavax's business, operations, performance, and prospects.

137. As the truth began to emerge regarding the true nature of HEPLISAV's BLA, and the insufficient process validation and manufacturing data compiled therein, the price of Dynavax's stock declined as the market processed each set of previously undisclosed facts. Each such disclosure removed a portion of the artificial inflation in the price of Dynavax's common stock and directly and proximately caused Plaintiffs and other Class members to suffer damages.

For example, following the publication of the Dynavax's receipt of the FDA's CRL, shares of Dynavax declined $0.96 per share, or 32.32%, to close on February 25, 2013 at $2.01 per share. Finally, Dynavax's common stock declined an additional $1.07 or 43.32%, to close on June 10, 2013 at $1.40 per share, following the last corrective disclosure pertaining to the FDA's request for additional safety and manufacturing data in order to approve ***any*** HEPLISAV indication.

138. Until shortly before Plaintiffs filed this Complaint, they were unaware of the facts alleged herein and could not have reasonably discovered Defendants' misrepresentations and omissions by the exercise of reasonable diligence.

CONTROL PERSON LIABILITY

139. The Individual Defendants are liable as direct participants with respect to the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of Section 20(a) of the Exchange Act, and each had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of Dynavax's business.

140. Specifically, because of their positions within the Company, the Individual Defendants possessed the power and authority to control the contents of Dynavax's annual and quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market, including those containing the materially false and misleading statements and omissions of material fact alleged herein. Each of the Individual Defendants, by reason of his/her respective management or board position, had the ability and opportunity to review copies of the Company's SEC filings, reports and press releases alleged herein to be misleading, prior to, or shortly after their issuance or to cause them to be corrected.

141. By virtue of their positions, the Individual Defendants had access to material non-public information. Each of the Individual Defendants knew or recklessly disregarded the fact

that the adverse facts specified herein had not been disclosed and were being concealed from the public, and that the positive representations which were being made were then materially false and misleading.

142. Defendants Kessel, SCP GP, and SGP LLC are liable as direct participants with respect to the wrongs complained of herein. In addition, Kessel, SCP GP, and SGP LLC, by reason of their status as managing members and/or general partners of SCP LP and/or SSP LLC, were "controlling persons" within the meaning of Section 20(a) of the Exchange Act, and each had the power and influence to cause SCP LP and/or SSP LLC, to engage in the unlawful conduct complained of herein. Because of their positions of control, Kessel, SCP GP, and SGP LLC were able to and did, directly or indirectly, control the conduct of SCP LP and/or SSP LLC's actions and business.

APPLICABILITY OF THE FRAUD ON THE MARKET DOCTRINE

143. The market for Dynavax's securities was an efficient market for the following reasons, among others:

a) Dynavax's stock was listed and actively traded on the NASDAQ, a highly efficient national market;

b) As a registered and regulated issuer of securities, Dynavax filed periodic reports with the SEC, in addition to the frequent voluntary dissemination of information;

c) Dynavax regularly communicated with public investors through established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures such as communications with the financial press and other similar reporting services;

d) Dynavax was followed by multiple analysts, which followed Dynavax's business and wrote reports which were publicly available and affected the public marketplace;

e) The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Dynavax's stock; and

f) Without knowledge of the misrepresented or omitted facts, Plaintiffs and other members of the Class purchased or otherwise acquired Dynavax stock between the time the Defendants made the material misrepresentations and omissions and the time that the truth was revealed, during which time the price of Dynavax stock was artificially inflated by Defendants' misrepresentations and omissions.

144. As a result of the above, the market for Dynavax securities promptly digested current information with respect to the Company from all publicly available sources and reflected such information in the security's price. Under these circumstances, all purchasers of Dynavax securities during the Class Period suffered similar injuries through their purchases of shares at prices which were artificially inflated by Defendants' misrepresentations and omissions. Thus, a presumption of reliance applies.

THE AFFILIATED UTE PRESUMPTION

145. At all relevant times, Plaintiffs and the Class reasonably relied upon Defendants to disclose material information as required by law and in the Company's SEC filings. Plaintiffs and the Class would not have purchased or otherwise acquired Dynavax securities at artificially inflated prices if Defendants had disclosed all material information as required. Thus, to the extent Defendants wrongfully failed to disclose material information concerning the inadequate BLA, validation program and manufacturing controls at the facilities related to the assurance of the quality of the commercial product for HEPLISAV, and the prospects for FDA approval of HEPLISAV's BLA, or otherwise, Plaintiffs are presumed to rely on Defendants' omissions as established by the Supreme Court in *Affiliated Ute Citizens v. U.S.*, 406 U.S. 128 (1972).

NO SAFE HARBOR

146. As alleged herein, Defendants acted with scienter because, at the time that they issued public documents and other statements in Dynavax's name, they knew or recklessly disregarded the fact that such statements were materially false and misleading or omitted

material fact. Moreover, Defendants knew that such documents and statements would be issued or disseminated to the investing public; knew that persons were likely to rely upon those misrepresentations and omissions; and knowingly and/or recklessly participated in the issuance and/or dissemination of such statements and/or documents as primary violators of the federal securities laws.

147. As set forth in detail in the Complaint, the Individual Defendants, by virtue of their control over, and/or receipt of Dynavax's materially misleading statements and/or their association with the Company which made them privy to confidential proprietary information concerning Dynavax which was used to artificially inflate financial prospects and which Individual Defendants caused or were informed of, participated in and knew of the fraudulent scheme alleged herein. With respect to non-forward looking statements and/or omissions, the Individual Defendants knew and/or recklessly disregarded the falsity and misleading nature of that information, which they caused to be disseminated to the investing public.

148. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made and/or were statements of historical fact. Rather, the statements alleged herein to be false and misleading all relate to facts and conditions existing at the time the statements were made. Moreover, meaningful statements did not identify important factors that could cause actual results to differ materially from those in any putative forward-looking statement.

149. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Dynavax who knew that those statements were false when made. None of the historic or present tense statements made

by Defendants were an assumption underlying or relating to any plan, projection, or statement of future economic performance, as they were neither stated to be such an assumption underlying or relating to any projection or statement of future economic performance when made nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

CLASS ACTION ALLEGATIONS

150. Plaintiffs bring the first and second counts of this Complaint pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of themselves and a class (the "Class") consisting of all persons who purchased or otherwise acquired Dynavax securities during the Class Period at artificially inflated prices, including but not limited to Dynavax common stock, during the Class Period, and who were damaged thereby. Excluded from the Class are the Defendants named herein, members of their immediate families, any firm, trust, partnership, corporation, officer, director or other individual or entity in which a Defendant has a controlling interest or which is related to or affiliated with any of the Defendants, and the legal representatives, heirs, successors-in-interest or assigns of such excluded persons.

151. Franklin brings the third, fourth, and fifth counts of this Complaint pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure as a class action on behalf of himself and persons and entities who purchased the common stock of Dynavax contemporaneously with sales by SCP LP and SSP LLC on October 16, 2012 and were damaged thereby ("the Subclass"). Excluded from the Subclass are the Defendants named herein, members of their immediate families, any firm, trust, partnership, corporation, officer, director, or other individual or entity in which a Defendant has a controlling interest or which is related to or affiliated with any of the Defendants, and the legal representatives, heirs, successors-in-interest, or assigns of such excluded persons.

152. Members of the Class and Subclass are so numerous and geographically dispersed that joinder of all members is impracticable. While the exact number of Class and Subclass members remains unknown at this time, as of November 5, 2013, Dynavax had 262,625,110

shares of common stock outstanding. Record owners, Class, and Subclass members can be identified from records maintained by Dynavax, or its transfer agent, and can be notified of the pendency of this action by mail and publication, using forms of notice similar to those customarily used in securities class actions.

153. Lead Plaintiff's and Franklin's claims are typical of the other members of the Class and Subclass because Lead Plaintiff and Franklin and all of the Class and Subclass members sustained damages that arose out of Defendants' unlawful conduct complained of herein.

154. Lead Plaintiff and Franklin will fairly and adequately protect the interests of the members of the Class and Subclass, and Lead Plaintiff and Franklin have no interests that are contrary to, or in conflict with, the interests of the Class and Subclass members that they seek to represent. Lead Plaintiff and Franklin have retained competent counsel experienced in class action litigation under the federal securities laws to ensure such protection and intend to prosecute this action vigorously.

155. A class action is superior to other methods for the fair and efficient adjudication of this controversy since joinder of all members of the Class and Subclass is impracticable. Furthermore, as the damages suffered by individual members of the Class and Subclass may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class and Subclass to individually seek redress for wrongs done to them. There will be no difficulty in the management of this action as a class action.

156. The prosecution of separate actions by individual Class and Subclass members would create a risk of inconsistent and varying adjudications, which could establish incompatible standards of conduct for Defendants. Questions of law and fact common to members of the Class and Subclass predominate over any questions that may affect only individual members, in that Defendants have acted on grounds generally applicable to the entire Class and Subclass. The questions of law and fact common to the Class and Subclass include, but are not limited to, the following:

a) Whether Defendants' acts violated the federal securities laws as alleged herein;

b) Whether Defendants' publicly disseminated statements during the Class Period omitted and/or misrepresented material facts;

c) Whether Defendants acted with scienter in omitting and/or misrepresenting material facts;

d) Whether the price of Dynavax securities was artificially inflated during the Class Period as a result of the material misrepresentations and omissions complained of herein;

e) Whether the Individual Defendants were controlling person as alleged herein; and

f) Whether members of the Class and Subclass have sustained damages and, if so, the proper measure of such damages.

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against Dynavax and the Individual Defendants

157. Plaintiffs reallege each allegation above as if fully set forth herein.

158. This claim is brought under Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, against Dynavax and the Individual Defendants. Defendants (1) employed devices, schemes and artifices to defraud; (2) made untrue statements of material fact and/or omitted material facts necessary to make the statements made not misleading; and (3) engaged in acts, practices and a course of business which operated as a fraud and deceit upon Plaintiffs and the Class, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

159. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal non-public, adverse material information about the Company's financial condition as reflected in the misrepresentations and omissions set forth above.

160. Defendants each had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth by failing to ascertain and to disclose such facts even though such facts were available to them, or deliberately refrained from taking steps necessary to discover whether the material facts were false or misleading.

161. As a result of Defendants' dissemination of materially false and misleading information and their failure to disclose material facts, Plaintiffs and the Class were misled into believing that the Company's statements and other disclosures were true, accurate, and complete.

162. Dynavax is liable for the acts of the Individual Defendants and other Company personnel referenced herein under the doctrine of respondeat superior, as those persons were acting as the officers, directors, and/or agents of Dynavax in taking the actions alleged herein.

163. Plaintiffs and the Class purchased Dynavax securities, without knowing that Defendants had misstated or omitted material facts about the Company's financial performance or prospects. In so doing, Plaintiffs and the Class relied directly or indirectly on false and misleading statements made by Defendants, and/or an absence of material adverse information that was known to Defendants or recklessly disregarded by them but not disclosed in Defendants' public statements. Plaintiffs and the Class were damaged as a result of their reliance on Defendants' false statements and misrepresentations and omissions of material facts.

164. At the time of Defendants' false statements, misrepresentations and omissions, Plaintiffs and the Class were unaware of their falsity and believed them to be true. Plaintiffs and the Class would not otherwise have purchased Dynavax securities had they known the truth about the matters discussed above.

165. Plaintiffs are filing this action within two years after discovery of the facts constituting the violation, including facts establishing scienter and other elements of Plaintiffs' claims, and within five years after the violations with respect to Plaintiffs' investments.

166. By virtue of the foregoing, Defendants have violated § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

167. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the Class have suffered damages in connection with their purchase of Dynavax securities.

COUNT II

For Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

168. Plaintiffs reallege each allegation above as if fully set forth herein.

169. Each of the Individual Defendants, by reason of their status as senior executive officers and/or directors of Dynavax, directly or indirectly, controlled the conduct of the Company's business and its representations to Plaintiffs and the Class, within the meaning of §20(a) of the Exchange Act. The Individual Defendants directly or indirectly controlled the content of the Company's SEC statements and press releases related to Plaintiffs' and the Class' investments in Dynavax securities within the meaning of §20(a) of the Exchange Act. Therefore, the Individual Defendants are jointly and severally liable for the Company's fraud, as alleged herein.

170. The Individual Defendants controlled and had the authority to control the content of the Company's SEC statements and press releases. Because of their close involvement in the everyday activities of the Company, and because of their wide-ranging supervisory authority, the Individual Defendants reviewed or had the opportunity to review these documents prior to their issuance, or could have prevented their issuance or caused them to be corrected.

171. The Individual Defendants knew or recklessly disregarded the fact that Dynavax's representations were materially false and misleading and/or omitted material facts when made. In so doing, the Individual Defendants did not act in good faith.

172. By virtue of their high-level positions and their participation in and awareness of Dynavax's operations and public statements, the Individual Defendants were able to and did influence and control Dynavax's decision-making, including controlling the content and dissemination of the documents that Plaintiffs and the Class contend contained materially false and misleading information and on which Plaintiffs and the Class relied.

173. The Individual Defendants had the power to control or influence the statements made giving rise to the securities violations alleged herein, and as set forth more fully above.

174. As set forth above, Defendants each violated §10(b) of the Exchange Act and Rule 10b-5, thereunder, by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, the Individual Defendants are also liable pursuant to §20(a) of the Exchange Act.

175. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiffs and the Class suffered damages in connection with their purchase of Dynavax securities.

COUNT III

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against SCP LP and SSP LLC

176. Franklin realleges each allegation above as if fully set forth herein.

177. On October 16, 2012, SCP LP sold 5,690,651 shares of Dynavax common stock at $4.72604 and SSP LLC sold 309,349 shares of Dynavax common stock at $4.72604.

178. At the time of the sale, SCP LP and SSP LLC and related entities had the right to appoint Kessel to the Dynavax Board of Directors and had done so. As a result, SCP LP and SSP LLC were in possession and aware of material non-public information concerning the Company, including the receipt of the Form 483 and the information contained therein relating to "significant objectionable conditions" identified by FDA inspectors in an August 2012 pre-approval inspection, and the deficiencies in the Company's BLA concerning the Company's process validation and manufacturing issues. SCP LP and SSP LLC, while in possession of material non-public adverse information about Dynavax, were under a duty to disclose that information or abstain from trading in Dynavax common stock. SCP LP and SSP LLC further knew that the non-public adverse information was material.

179. In conducting the transaction, neither SCP LP nor SSP LLC, nor anyone else disclosed the material non-public information to the investing public.

180. Franklin and the members of the Subclass traded contemporaneously with SCP LP and SSP LLC.

181. Franklin and the members of the Subclass suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Dynavax common stock. Franklin and the members of the Subclass would not have purchased Dynavax common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by SCP LP and SSP LLC's failure to disclose material non-public information, or if they had been aware of the material non-public information SCP LP and SSP LLC failed to disclose.

COUNT IV

For Violations of Section 20A of the Exchange Act Against SCP LP and SSP LLC

182. Plaintiff Franklin realleges each allegation above as if fully set forth herein.

183. This Claim is brought against SCP LP and SSP LLC by Franklin and the Subclass for violation of Section 20A of the Exchange Act, 15 U.S.C. § 78t-1. Plaintiff Franklin and the Subclass purchased Dynavax common stock contemporaneously with sales of Dynavax common stock by the Defendants named in this count.

184. By virtue of Kessel's position on the Board and the provisions of the Registration Rights Agreement, SCP LP and SSP LLC were in possession of material, non-public information about the Company at the time of their sales of Dynavax common stock.

185. By virtue of their participation in the scheme to defraud investors described herein, and their sales of stock while in possession of material, non-public information about the adverse information detailed herein, SCP LP and SSP LLC violated the Exchange Act and applicable rules and regulations thereunder.

186. Franklin and the Subclass purchased shares of Dynavax common stock contemporaneously with the sales of Dynavax common stock by SCP LP and SSP LLC. As a result, Plaintiff and the Subclass: (i) suffered substantial damages in that they purchased Dynavax common stock without knowledge of the insufficient process validation program and

manufacturing controls data submitted in the BLA, the failed pre-approval inspection of the Dusseldorf facility, and the issuance of the Form 483 to Dynavax, along with the manufacturing problems identified therein; and (ii) would not have purchased Dynavax common stock at the prices Plaintiff Franklin and the Subclass paid, or at all, if they had been aware that the market prices had been artificially inflated by Defendants' false and misleading statements and/or omissions.

187. SCP LP and SSP LLC are required to account for all such stock sales and to disgorge their profits or losses avoided.

COUNT V

For Violations of Section 20(a) of the Exchange Act Against Defendants Kessel, SGP LLC, and SCP GP

188. Plaintiff Franklin realleges each allegation above as if fully set forth herein.

189. Kessel, SGP LLC, and SCP GP, were each a managing member, general partner, or managing member of a general partner of SCP LP and/or SSP LLC. By reason of their status as managing member, general partner, or managing member of a general partner of Symphony SCP LP and/or SSP LLC, directly or indirectly, controlled the conduct of SCP LP and/or SSP LLC in the sale of Dynavax common stock, within the meaning of §20(a) of the Exchange Act. Therefore, Kessel, SGP LLC, and SCP GP are jointly and severally liable for SCP LP and SSP LLC's violations of Section 20A, as alleged herein.

190. Kessel, SGP LLC, and SCP GP, knew or recklessly disregarded the fact that SGP LLC, and SCP GP failed to disclose material non-public information concerning the Company, including Dynavax's receipt of the Form 483 and the information contained therein relating to "significant objectionable conditions" identified by FDA inspectors in an August 2012 pre-approval inspection, and the deficiencies in the Company's BLA concerning the Company's process validation and manufacturing issues, and while in possession of this material non-public information SGP LLC and SCP GP collectively sold 6 million shares of Dynavax common stock while in possession of material non-public adverse information about Dynavax. In permitting

and signing documents necessary for the transaction to be completed Kessel, SGP LLC, and SCP GP did not act in good faith.

191. By virtue of their high-level positions and their participation in and awareness of Dynavax's operations and public statements, Kessel, SGP LLC, and SCP GP were able to and did influence and control SGP LLC, and SCP GP's decision-making, including controlling the content and dissemination of the documents that Franklin and the Subclass contend contained materially false and misleading information and omissions and on which Franklin and the Subclass relied.

192. Kessel, SGP LLC, and SCP GP had the power to control or influence the transactions and statements made giving rise to the securities violations alleged herein, and as set forth more fully above.

193. As set forth above, Defendants SGP LLC, and SCP GP each violated §§10(b) and 20A of the Exchange Act and Rule 10b-5, thereunder, by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, Kessel, SGP LLC, and SCP GP are also liable pursuant to §20(a) of the Exchange Act.

194. As a direct and proximate result of Kessel, SGP LLC, and SCP GP's wrongful conduct, Plaintiff Franklin and the Subclass suffered damages in connection with their purchase of Dynavax common stock.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs on behalf of themselves and the Class, pray for relief and judgment including:

A. Determining that Counts I – V of this action are a proper class action under Federal Rules of Civil Procedure 23, certifying Plaintiffs as Class representatives under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs' counsel as Lead Counsel;

B. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of

Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-judgment interest, as allowed by law;

C. Awarding rescissory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all injuries sustained as a result of Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-judgment interest, as allowed by law;

D. Awarding disgorgement of SCP LP's and SSP LLC's profits or losses avoided;

E. Awarding extraordinary, equitable, and/or injunctive relief as permitted by law (including, but not limited to, rescission);

F. Awarding Plaintiffs and the Class their costs and expenses incurred in this action, including reasonable counsel fees and expert fees; and

G. Awarding such other and further relief as may be just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury on all triable claims.

Dated: September 10, 2014

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